RESEARCH PAPER

Immunomodulatory and Therapeutic Role of Swarna Prashan in Pediatric Recurrent Respiratory Tract Infections

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Abstract

Background: Pediatric Recurrent Respiratory Tract Infections (RRTIs) represent a major global clinical challenge, precipitating substantial morbidity, frequent hospitalization, school absenteeism, and the rampant misuse of empirical antibiotics leading to antimicrobial resistance. In Ayurvedic pediatric medicine (*Kaumarbhritya*), the classical electuary *Swarna Prashan* (comprising calcinated gold nanoparticles [*Swarna Bhasma*], clarified cow butter [*Ghrita*], and raw processed honey [*Madhu*], frequently fortified with *Medhya* and *Rasayana* herbs such as *Bacopa monnieri* and *Acorus calamus*) is prescribed as a bio-enhancer and immune-modulator (*Vyadhikshamatva* enhancer).

Objective: To systematically evaluate and synthesize the biochemical, immunological, pharmacological, and clinical evidence elucidating the immunomodulatory and therapeutic role of *Swarna Prashan* in pediatric RRTIs.

Methods: A multi-dimensional narrative review and meta-synthesis of classical texts (*Kashyapa Samhita*, *Sushruta Samhita*, *Charaka Samhita*) alongside contemporary biomedical literature, physicochemical nanoparticle analyses (TEM, XRD, ICP-MS/OES), in vitro/in vivo immunological bioassays, and randomized/controlled clinical trials evaluating *Swarna Prashan* in children aged 0–16 years with RRTIs.

Results: Physicochemical characterization confirms *Swarna Bhasma* as a therapeutic nano-colloid (predominantly 20–100 nm crystallites) conjugated to organic ligands during repeated incineration (*Puta*). Mechanistically, *Swarna Prashan* exerts pleiotropic immune regulation: it enhances macrophage phagocytic index and antigen presentation, polarizes CD4+ T helper responses toward a balanced Th1 phenotype, modulates mucosal secretory immunoglobulin A (sIgA) and serum IgG, downregulates pro-inflammatory hyper-responsiveness (TNF-α, IL-6) while dampening atopic Th2 hyper-reactivity (IL-4, IgE), and provides potent antioxidant free-radical scavenging. Clinical trials demonstrate statistically significant reductions in annual RRTI frequency (mean episode decrease of 35–55%), shorter symptom duration (rhinorrhea, cough, fever), reduced antibiotic reliance, and marked improvements in anthropometric parameters without detectable hepatic, renal, or systemic toxicity.

Conclusions: *Swarna Prashan* functions as a multi-target, biomacromolecular-delivery platform exhibiting robust non-specific immunoprophylaxis and mucosal barrier reinforcement. It represents a scientifically viable, integrative modality to mitigate pediatric RRTIs and counter antibiotic overprescription. Standardized industrial production, strict elemental batch profiling, and large multicenter phase-III trials are warranted.

Keywords: Swarna Prashan, Swarna Bhasma, Gold Nanoparticles, Recurrent Respiratory Tract Infections, Pediatric Immunity, *Vyadhikshamatva*, Immunomodulation, *Kaumarbhritya*.

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Introduction and Clinical Burden

Recurrent Respiratory Tract Infections (RRTIs) in the pediatric population remain among the most frequent diagnoses encountered in primary health care and outpatient pediatrics worldwide (Bhaskaran et al., 2019). Typically defined as more than six to eight upper respiratory tract episodes (pharyngitis, tonsillitis, rhinosinusitis, otitis media) or three or more lower respiratory episodes (bronchitis, bronchiolitis, pneumonia) per year in children younger than six years, RRTIs place an intense physiological and psycho-emotional burden on patients and their caregivers (Singhal et al., 2021).

While the majority of infections are self-limiting viral pathogens (e.g., Human Rhinovirus, Respiratory Syncytial Virus, Adenovirus, Parainfluenza, and Coronaviruses), secondary bacterial invasions by *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis* frequently supervene (Ahir et al., 2018). The management paradigm in conventional pediatrics relies predominantly on symptomatic relief (antipyretics, nasal decongestants, systemic antihistamines) and the recurrent, often inappropriate empirical deployment of broad-spectrum antibacterial agents (Khedekar et al., 2016). Repeated antibiotic exposures disrupt the developing gut-lung microbiome axis, predispose infants to dysbiosis, amplify allergic diathesis, and drive global antimicrobial resistance (Saini et al., 2023).

Consequently, pediatric medicine is actively

exploring prophylactic and biological immunomodulatory interventions aimed at strengthening host systemic and mucosal defenses rather than merely suppressing clinical symptoms post-infection. In this context, traditional Indian medicine (Ayurveda), particularly its pediatric specialty (*Kaumarbhritya*), offers systematic preventative frameworks categorized under *Vyadhikshamatva* (host resistance/immunity) and *Lehana* (nutritive electuaries) (Kashyapa et al., 2010; Vagbhata et al., 2014).

Central to this prophylactic repertoire is **Swarna Prashan** (also termed *Suvarnaprashana*, *Swarna Bindu Prashana*, or *Suvarna Amrita Prashana*), a specialized herbo-metallic formulation first codified by Sage Kashyapa in the fundamental pediatric treatise *Kashyapa Samhita* (Kashyapa et al., 2010). Classically prepared by incorporating micro- and nano-processed metallic gold (*Swarna Bhasma*) into a matrix of clarified cow butter (*Ghrita*) and wild honey (*Madhu*), often fortified with herbal decoctions of neuro-immunological adaptogens (*Brahmi*, *Vacha*, *Shankhpushpi*, *Guduchi*), *Swarna Prashan* has been administered for centuries to augment physical growth, neurodevelopment (*Medha*), metabolic vigor (*Agni*), and disease resistance (*Bala*) (Jyothy et al., 2014; Shahadat et al., 2022).

Modern nanomedical and immunopharmacological investigations suggest that *Swarna Prashan* is not an archaic metallic potion, but rather a sophisticated, naturally stabilized, lipid-emulsified gold nanoparticle delivery platform capable of interfacing directly with gut-associated lymphoid tissue (GALT) to reprogram innate and adaptive immune cell signaling (Paul & Sharma, 2011; Bali et al., 2026). This article provides a comprehensive, multi-layered scientific critique of the theoretical foundations, physicochemical morphology, cellular and humoral immunomodulatory mechanisms, clinical outcomes, toxicology, and prospective translational avenues of *Swarna Prashan* in pediatric RRTIs. (Gupta et al., 2024)

Etiopathogenesis of Pediatric RRTIs: Biomedical and Ayurvedic Paradigms

Understanding why young children display an inherent vulnerability to RRTIs requires cross-referencing conventional mucosal immunology with classical Ayurvedic constitutional doctrine.

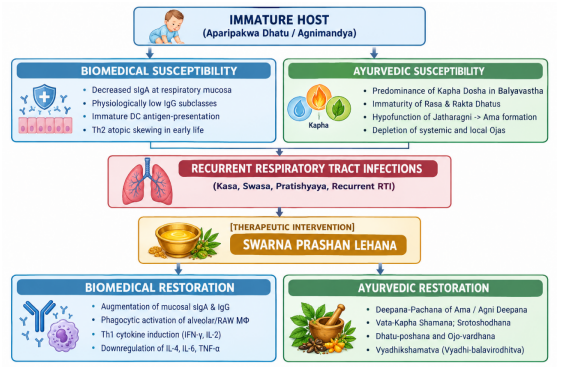


Figure 1. Proposed Biomedical and Ayurvedic Pathways of Susceptibility, Recurrent Respiratory Tract Infections, and Potential Restorative Effects of Swarna Prashan Lehana in Children.

The Biomedical Window of Susceptibility

The pediatric respiratory tract experiences an immunologic vulnerable window between approximately 6 months and 5 years of age (Bhaskaran et al., 2019):

Maternal Antibody Waning: Transplacentally transferred maternal IgG catabolizes progressively across the first 6 months of extrauterine life.

Delayed Endogenous Immunoglobulin Synthesis: Endogenous pediatric serum IgG (particularly IgG1 and IgG2 subclasses) and secretory IgA (sIgA) concentrations do not achieve adult physiological thresholds until middle-to-late childhood (Rana et al., 2015). Low baseline mucosal sIgA fails to adequately neutralize respiratory viruses at the ciliated nasopharyngeal epithelium.

Immature Cellular Cytotoxicity: Pediatric dendritic cells (DCs) exhibit diminished surface expression of major histocompatibility complex class II (MHC-II) and co-stimulatory markers (CD80, CD86), leading to blunted Th1 polarization and decreased early interferon-gamma (IFN-γ) synthesis (Saini et al., 2023).

Environmental Triggers: Exposure to crowded daycare environments, air pollutants ($PM_{2.5}$, nitrogen dioxide), secondhand tobacco smoke, and premature cessation of exclusive breastfeeding exacerbate mucosal barrier dysfunction.

The Ayurvedic Construct of *Balyavastha*, *Kapha Prakopa*, and *Vyadhikshamatva*

Classical Ayurvedic pediatrics describes childhood (*Balyavastha*, extending up to 16 years) as a physiologically distinct state characterized by:

- **Aparipakwa Dhatu:** The structural body tissues (*Dhatus*) are tender, immature, and continually undergoing rapid differentiation and growth (Kashyapa et al., 2010).
- **Kapha Dosha Dominance:** Childhood is

naturally dominated by *Kapha Dosha*, the bio-principle governing structural cohesion, bodily fluids, and growth. However, this physiological excess of *Kapha* predisposes children to excess mucus accumulation, stasis, and *Pratishyaya* (coryza/rhinitis), *Kasa* (cough), and *Swasa* (bronchial wheezing/dyspnea) (Vagbhata et al., 2014).

- **Manda Agni (Sluggish Digestive-Metabolic Fire):** Pediatric metabolic fire (*Jatharagni* and *Dhatvagni*) is inherently delicate (*Alpa Agni*). Indigestion generates *Ama* (endogenous endotoxic metabolic residue), which travels through circulating *Rasa Dhatu*, clogs micro-circulatory channels (*Srotas*, specifically *Pranavaha Srotas*), and impairs local tissue resistance (Charaka et al., 2011).
- **Ojas Deficit:** *Ojas* is the quintessential essence of all seven matured *Dhatus* and the biological substrate of *Vyadhikshamatva* (immunity) (Khedekar et al., 2015). Acharya Chakrapanidatta differentiates *Vyadhikshamatva* into two components:
    1. *Vyadhi-utpada-pratibandhakatva:* The ability to resist the initial manifestation and establishment of a pathogen or disease.
    2. *Vyadhi-bala-virodhitva:* The physiological capacity to inhibit the virulent progression, severity, and chronicity of an established disease (Charaka et al., 2011).

In pediatric RRTIs, a vicious cycle develops: *Manda Agni* → *Ama* → *Pranavaha Srotorodha* → *Kapha-Vata Sanchaya* in lungs → *Ojo-kshaya* → recurrent pathogen vulnerability. *Swarna Prashan* is explicitly designed to break this cycle by simultaneously stimulating *Agni*, clearing *Srotas*, and directly nourishing *Ojas* (Kashyapa et al., 2010; Jyothy et al., 2014).

Classical Textual Foundation and Formulation Pharmaceutics

The primary textual authority for administering gold to neonates and growing infants resides in the *Lehana Adhyaya* (Chapter on Electuaries) of the *Kashyapa Samhita*:

"Suvarna prashanam hyetath medhagnibala vardhanam |
Ayushyam mangalam punyam vrushyam grahapaham ||
Masat paramamedhavi vyadhibhirna cha dhrushyate |
Shadbhir masai shrutadhara suvarnaprashanad bhavet ||"

— (*Kashyapa Samhita, Sutrasthana, Lehanadhyaya*, 8:45–46) (Kashyapa et al., 2010)

Classical Preparation Modalities

Historically, Kashyapa described the immediate bedside extemporaneous method: a clean, authenticated piece or leaf of metallic gold was rubbed on a sterile stone slab (*Shila*) in a circular direction with sterile water, creating a micro-particulate paste. This suspension was thoroughly blended (*Pramathya*) with equal or customized proportions of pure cow's ghee (*Ghrita*) and raw unprocessed honey (*Madhu*), and administered to the infant on an empty stomach facing eastward (Kashyapa et al., 2010; Singhal et al., 2021).

As alchemical rasashastra developed through the medieval era, this physical rubbing technique evolved into standardized thermo-chemical calcination yielding **Swarna Bhasma** (incinerated gold calx) (Charaka et al., 2011; Sharma et al., 1994). This progression replaced crude macro-particulate metallic flakes with homogeneous, biocompatible, sub-micron and nano-scale gold crystallites (Khedekar et al., 2016).

Step-by-Step Modern Pharmaceutics of Swarna Bhasma

The pharmaceutical processing of gold into therapeutic *Bhasma* follows strict canonical protocols ensuring detoxification, size reduction, and organo-metallic complexation:

Shodhana (Purification/Detoxification): 24-karat pure elemental gold foils (*99.99%* purity) are heated to red heat and repeatedly quenched (*Nirvapana*) in classical liquid media: sesame oil (*Tila Taila*), buttermilk (*Takra*), fermented gruel (*Kanji*), cow's urine (*Gomutra*), and a decoction of *Kulattha* (*Dolichos biflorus*). This thermal shock alters tensile strength, induces micro-fractures, and eliminates surface contaminants (Mitra et al., 2002; Kapoor, 2010).

Marana (Incineration/Calcination): Purified gold sheets are cut into tiny fragments, amalgamated with purified elemental mercury (*Shuddha Parada*) and sulfur (*Shuddha Gandhaka*) to form a *Kajjali* amalgam, or triturated (*Bhavana*) with potent plant juices (e.g., *Aloe vera* [*Kumari*], *Rosa centifolia* [*Gulab*], or *Cassia fistula*).

Puta (Graded Heating Cycles): The triturated paste is compressed into flat pellets (*Chakrikas*), dried, sealed inside double-earthen crucibles (*Sharava Samputa*), and subjected to specialized subterranean furnaces (*Gaja Puta*, generating controlled temperatures reaching 750°C–850°C). This cycle of trituration, drying, and subterranean calcination is repeated 30 to 42 times (Sharma et al., 1994; Khedekar et al., 2016).

Bhasma Pariksha (Classical Quality Testing): The final ash must pass classical physical quality tests:

- *Varitara:* Floats entirely on the surface tension of water, confirming sub-sieve micro/nanoscale particulate size.
- *Rekhapurnata:* Particles penetrate fine finger skin ridges without abrasive sensation.
- *Niswadu:* Taste-free (inert to lingual papillae).
- *Apunarbhava & Niruttha:* Inability to re-aggregate or reduce back to physical metallic gold when fused with fluxing agents (borax, silver, lead) under intense heat (Sharma et al., 1994).

Nanomaterial Characterization of Swarna Bhasma and the Tri-Matrix Delivery System

Modern analytical instrumentation has confirmed that *Swarna Bhasma* is an early pioneer of inorganic nanomedicine.

Table 1. Analytical Characterization and Physicochemical Properties of Swarna Bhasma

Analytical Modality	Investigated Parameter	Observed Physicochemical Findings in Swarna Bhasma
Transmission Electron Microscopy (TEM)	Particle morphology & sizing	Spherical, globular, and polyhedral nanoparticles ranging from 15 to 100 nm (mean diameter 28–56 nm) (Paul & Sharma, 2011; Saini et al., 2023).
Scanning Electron Microscopy (SEM)	Agglomeration and surface topology	Highly porous, sponge-like aggregated micro-clusters composed of fused nanometer crystallites
		(Khedekar et al., 2016).
X-Ray Diffraction (XRD)	Crystalline lattice structure	Distinct diffraction peaks matching face-centered cubic (fcc) zero-valent elemental gold (Au^0) alongside traces of oxidized gold (Au_2O_3) (Mitra et al., 2002; Saini et al., 2023).
Energy-Dispersive X-Ray Spectroscopy (EDS / EDX)	Elemental composition	Elemental gold (Au) comprises 52.3% to 92.4% w/w; oxygen, carbon, and biologically active macro/trace minerals (Fe, Ca, Mg, K) constitute the balance (Khedekar et al., 2016).
Dynamic Light Scattering (DLS) & Zeta Potential	Colloidal hydrodynamic diameter & charge	Hydrodynamic diameter 120–280 nm in suspension; negative zeta potential (-18 to -28

Analytical Modality	Investigated Parameter	Observed Physicochemical Findings in Swarna Bhasma
		mV), indicating good electrostatic repulsion and dispersion stability (Bali et al., 2026).
Fourier-Transform Infrared (FT-IR)	Organic surface capping	Vibrational stretching modes corresponding to carboxyl (-COOH), amino (-NH2), and phenolic hydroxyl groups derived from herbal *Bhavana* media, confirming biopolymer capping (Paul & Sharma, 2011).

The Honey-Ghee Lipid Nanocarrier Complex

The classical requirement of delivering *Swarna Bhasma* suspended in *Madhu* (honey) and *Ghrita* (clarified butter) represents a functional biomimetic drug delivery vehicle:

- **The Ghee Component (Lipid Matrix):** Clarified cow butter consists predominantly of medium- and short-chain triglycerides, butyric acid, docosahexaenoic acid (DHA), and lipophilic vitamins (A, D, E, K). Gold nanoparticles disperse into these lipophilic micelles, facilitating passive transmucosal uptake across the sublingual mucosa and specialized intestinal M cells overlying Peyer's patches (Jyothy et al., 2014; Bali et al., 2026). This bypasses first-pass hepatic metabolism and delivers nanoparticles directly to systemic circulation and intestinal lymphatics.
- **The Honey Component (Hydrophilic Matrix & Fructose Emulsifier):** Raw honey provides high concentrations of monosaccharides (fructose, glucose), organic acids (gluconic acid), hydrogen peroxide precursors, and polyphenolic flavonoids (chrysin, pinocembrin). Honey stabilizes the hydrophobic lipid-gold suspension, creating a thermodynamically stable oil-in-water nano-emulsion that protects mucosal tight junctions from oxidative breakdown (Bali et al., 2026).
- **The Unequal Proportion Doctrine:** Classical texts explicitly instruct that honey and ghee must **never** be combined in equal proportions by weight or volume. In equal quantities, differing crystallization velocities and enzymatic cross-reactions induce physicochemical rancidity (*Viruddha Ahara*). In *Swarna Prashan*, a ratio of 2:1 or 4:1 (ghee to honey, or vice versa, depending on the child's *Prakriti*) is maintained to preserve emulsion stability (Kashyapa et al., 2010; Charaka et al., 2011).

Immunomodulatory Mechanisms in Respiratory Defense

The therapeutic efficacy of *Swarna Prashan* against pediatric RRTIs stems from coordinated actions on mucosal barriers, innate surveillance cells, and adaptive lymphocyte differentiation.

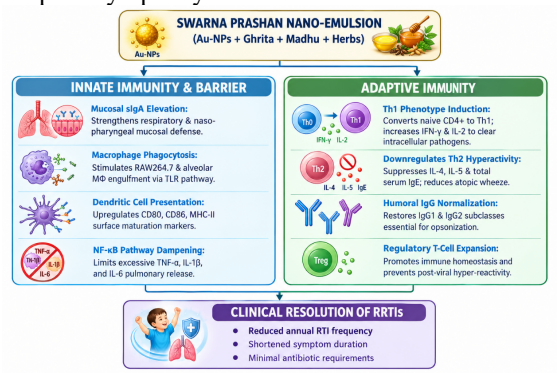


Figure 2. Proposed Immunomodulatory Pathways of Swarna Prashan Nano-Emulsion

Augmentation of Mucosal Secretory IgA (sIgA)

Secretory IgA serves as the initial immunological barrier across the nasopharyngeal, tracheobronchial, and intestinal mucosa. In pediatric RRTIs, low baseline sIgA levels permit respiratory viruses to adhere to mucosal epithelial receptors (e.g., ICAM-1). Clinical evaluations of modified *Swarna Prashan* have shown significant post-intervention increases in both salivary and mucosal sIgA concentrations (Shahadat et al., 2022). This increase promotes immune exclusion: gold-conjugated

immunoglobulins bind viral capsids and bacterial adhesins, sterically preventing colonization and facilitating mucociliary clearance without triggering inflammatory tissue destruction.

Macrophage Priming and Phagocytic Index

Monocytes and tissue-resident alveolar macrophages represent the front-line cellular defense against airborne pathogens. In vitro bioassays evaluating *Swarna Bhasma* on RAW 264.7 macrophage lines demonstrate that therapeutic concentrations ($10 - 40\ \mu$g/mL) significantly augment the phagocytic index, cell viability, and microbicidal clearance capacity (Saini et al., 2023). Surface-stabilized gold nanoparticles interact with cell-surface scavenger receptors and Toll-like receptors (TLR-2 and TLR-4), initiating a controlled intracellular signaling cascade. This triggers gentle lysosomal enzymatic activation, reactive oxygen species generation within phagolysosomes, and rapid degradation of internalized bacterial pathogens (e.g., *S. pneumoniae*) without causing systemic cytotoxicity (Saini et al., 2023).

Dendritic Cell Maturation and Antigen Presentation

Dendritic cells (DCs) bridge innate viral detection and adaptive lymphocyte activation. Studies reveal that *Swarna Bhasma* substantially upregulates the surface expression of key co-stimulatory molecules (CD80, CD86) and Major Histocompatibility Complex class II (MHC-II) on antigen-presenting cells (Saini et al., 2023). This provides the necessary two-signal threshold for antigen-inexperienced pediatric T cells, enabling effective immunological priming against transient respiratory pathogens.

Th1/Th2 Cytokine Balancing and Attenuation of Atopic Tendency

Young children frequently display a default Th2 bias, driving atopic respiratory disorders, allergic rhinitis, and reactive airway hyper-responsiveness. Repeated viral infections exacerbate this polarization by triggering airway eosinophilia and IL-4, IL-5, and IL-13 secretion.

- *Swarna Prashan* helps counterbalance this atopic cascade. Experimental models show that *Swarna Bhasma* directs antigen-experienced CD4+ T helper cells toward a protective **Th1 phenotype**, upregulating interferon-gamma (IFN-γ) and interleukin-2 (IL-2) synthesis (Saini et al., 2023). IFN-γ suppresses viral replication inside bronchial epithelial cells and promotes cytotoxic CD8+ T-cell and Natural Killer (NK) cell activation.
- Simultaneously, the formulation downregulates exaggerated systemic IL-4 and total IgE levels (Rahman et al., 2024; Khedekar et al., 2023). This reduces bronchial smooth muscle spasms, mucosal edema, and subsequent wheezing episodes.

Anti-Inflammatory Dampening of the NF-κB Signaling Pathway

While an effective immune response requires pathogen recognition, pediatric respiratory morbidity frequently stems from unconstrained inflammation: excessive pulmonary neutrophil infiltration and cytokine storming driven by Nuclear Factor-kappa B (NF-κB). Gold nanoparticles covalently interact with cysteine residues within the kappa$Bkinase(IKK)complex, blockingI$ kappa $BphosphorylationandhaltingsubsequentNF$ kappa B nuclear translocation (Paul & Sharma, 2011; Singhal et al., 2021).

This targeted down-modulation reduces excessive transcription of pro-inflammatory mediators (TNF-α, IL-1beta, IL-6, and inducible nitric oxide synthase [iNOS]), preventing post-infectious bronchial epithelial injury while preserving normal pathogen clearance mechanisms.

Antioxidant Protection and Free Radical Scavenging

Pediatric lung parenchymal tissues are susceptible to lipid peroxidation during viral respiratory paroxysms. *Swarna Bhasma* and the polyphenols in processed *Ghrita* and *Madhu* significantly upregulate endogenous antioxidant enzymes: Superoxide Dismutase (SOD), Catalase (CAT), and reduced Glutathione (GSH) (Sharma et al., 2012; Shahadat et al., 2022). This scavenges harmful superoxide anions ($O_2^{\cdot-}$) and hydroxyl radicals ($^{\cdot}OH$), maintaining alveolar membrane integrity.

Synergistic Phytochemical Ingredients in Fortified Formulations

While canonical *Swarna Prashan* uses gold, ghee, and honey, classical pediatric practice often incorporates specific neuro-immunological and respiratory herbal extracts (*Medhya* and *Rasayana* herbs) to broaden its therapeutic profile (Ahir et al., 2018; Singhal et al., 2021):



Figure 3. Components and proposed functional roles of a fortified Swarna Prashan formulation

Bioactive Constituents: Triterpenoid saponins (Bacosides A and B), bacopasides, and flavonoids.

- **Mechanism in RRTIs:** While celebrated for enhancing cognitive function (*Medhya Rasayana*), *Bacopa* exhibits significant mast cell stabilizing, anti-spasmodic, and anti-inflammatory properties (Jyothy et al.,

2014). It inhibits respiratory smooth muscle contractions induced by histamine and acetylcholine, preventing reflex bronchospasm during viral bronchitis.

***Acorus calamus* (Vacha)**

- **Bioactive Constituents:** α- and β-asarone, acoramen, and sesquiterpenoids.
- **Mechanism in RRTIs:** *Vacha* acts as a potent mucolytic, expectorant, and speech enhancer. Its essential oils relax tracheal smooth muscle, thin viscid bronchial secretions, and expedite mucociliary transport in productive pediatric coughs (Singhal et al., 2021). Classical protocols often use *Suvarna Vacha* (a purified gold wire rubbed alongside dried *Acorus calamus* rhizomes).

***Tinospora cordifolia* (Guduchi)**

- **Bioactive Constituents:** Cordifolioside A, tinocordiside, clerodane furano-diterpenes, and arabinogalactan polysaccharides.
- **Mechanism in RRTIs:** *Guduchi* is among Ayurveda's most validated immunostimulants (*Rasayana*). Its arabinogalactan polymers activate complement pathways and prime peripheral polymorphonuclear neutrophils, enhancing bactericidal killing during intercurrent bacterial superinfections (Shahadat et al., 2022).

***Glycyrrhiza glabra* (Yashtimadhu)**

- **Bioactive Constituents:** Glycyrrhizin, glycyrrhetinic acid, isoliquiritigenin.
- **Mechanism in RRTIs:** Glycyrrhizin directly inhibits the replication of multiple single- and double-stranded respiratory viruses (including Influenza A and Coronaviruses) by interrupting cellular attachment, uncoating, and gene transcription (Saini et al., 2023). Concurrently, its demulcent properties soothe inflamed pharyngeal and laryngeal mucosa.

Clinical Trials and Systematic Evidence Synthesis

Over the past two decades, clinical trials across pediatric tertiary Ayurvedic centers and collaborative medical institutions have evaluated *Swarna Prashan* for infant health, immune status, and pediatric recurrent respiratory illness.

Table 2. Clinical Evidence on Suvarna Prashana in Pediatric Populations

Lead Investigator & Year	Study Design & Sample Size (N)	Target Population & Age Bracket	Intervention & Dosing Regimen	Assessed Clinical & Lab Parameters	Key Reported Outcomes
Bhaskaran et al. (2019)	Randomized Controlled Trial (RCT); $N = 45$	Full-term healthy infants (1 day to 12 months)	Trial: *Swarna Prashan* (1–2 drops daily for 28 days); Control: Honey + Ghee vehicle	Serum IgG, hematology (WBC, Hb), anthropometry, hepatic (SGOT/SGPT) and renal (BUN/	84.5% of trial infants maintained/ normalized physiological serum IgG compared to 60% in controls; normal dentition; no hepatic or renal deranged men

Lead Investigator & Year	Study Design & Sample Size (N)	Target Population & Age Bracket	Intervention & Dosing Regimen	Assessed Clinical & Lab Parameters	Key Reported Outcomes
				Cr) profiles	ts; zero adverse events reported.
Rana et al. (2015)	Prospective Clinical Trial; *N = 60*	Children (3 to 5 years) presenting with poor immunity	Trial: Modified *Swarnamrita Prashana* daily for 30 consecutive days; Control: Pla	Serum IgG, total protein, anthropometry (weight, height), episode tracker	Statistically significant ($p < 0.01$) elevation in serum IgG; significant weight gain; noticeable reduction in
			ceb o syrup	for infections	quarterly respiratory infection rates.
Ahir et al. (2018)	Controlled Clinical Study; *N = 60*	Children (2 to 10 years) with documented Recurrent UR	Group A: *Suvarna Prashan* drops on *Pushya Nakshatra* for 6 cycles; Grou	Frequency of URTI episodes, episode duration, symptom sever	51.4% reduction in recurring infection episodes in the intervention arm; average recovery time shortene

Lead Investigator & Year	Study Design & Sample Size (N)	Target Population & Age Bracket	Intervention & Dosing Regimen	Assessed Clinical & Lab Parameters	Key Reported Outcomes
		TIs	pB: Standard pediatric care	ity scoring (rhinorrhea, cough, fever)	d from 6.8 days to 3.2 days; significant drop in symptomatic sick leaves.
Shahadat et al. (2022)	Systematic Review / Pooled Cohort An	Pediatric cohorts (0 to 16 years) ac	Varied protocols: Daily low-dose vs. Mo	Upper/lower RTI incidence, gastrointes	Significant pooled reduction in annual respiratory episodes

Lead Investigator & Year	Study Design & Sample Size (N)	Target Population & Age Bracket	Intervention & Dosing Regimen	Assessed Clinical & Lab Parameters	Key Reported Outcomes
	aly sis	ross multiple clinical studies	nthly *Pushya Nakshatra* administrations	tinal infections, salivary sIgA, general vitality (*Bala*)	from an average of 6.23 to 4.10 episodes ($p < 0.001$); gastrointestinal infections reduced; physical (*Dehabala*) and digestive (*Agnibala*) indices improve

Lead Investigator & Year	Study Design & Sample Size (N)	Target Population & Age Bracket	Intervention & Dosing Regimen	Assessed Clinical & Lab Parameters	Key Reported Outcomes
					d.
Patel et al. (2017)	Single-Arm Prospective Interventional; *N = 50*	Children (6 months to 10 years)	*Suvarna prashan* drops administered once monthly on *Pushya Nakshatra* across 12 months	Mid-upper arm circumference (MUAC), height, weight, recurring cough/cold frequency	Statistically significant improvement in MUAC ($p < 0.001$) and body weight; parents reported marked decrease in recurrent seasonal sickness and lower antibiotic reliance.

Methodological Critique: Daily vs. Monthly Intermittent Administration

A central debate in pediatric Ayurvedic practice concerns dosing frequency:

The Monthly Pushya Nakshatra Protocol: In many public health campaigns across India, *Swarna Prashan* is administered once every 27 days on the astronomical day of *Pushya Nakshatra*. Classical rationale holds that this lunar constellation enhances cellular receptivity and metabolic absorption (*Yogavahi* capacity) (Singhal et al., 2021). While convenient for community-wide public drives, pharmacological analyses suggest that a single monthly dose may produce intermittent sub-therapeutic plasma spikes that are less suitable for correcting ongoing chronic immune deficiencies (Jyothy et al., 2014).

The Daily Low-Dose Classical Regimen: As originally outlined in the *Kashyapa Samhita*, the formulation was intended for continuous daily consumption: for one month (*Masat paramamedhavi vyadhibhirna cha dhrushyate*—conferring disease resistance) or up to six months (*Shadbhir masai shrutadhara*—conferring heightened intellect and memory) (Kashyapa et al., 2010). Clinical trials

administering daily low-dose *Swarna Prashan* (0.15–0.30 mg of *Swarna Bhasma* equivalent per kg body weight) demonstrate more consistent, sustained improvements in serum IgG, salivary sIgA, and mucosal defense than single-dose monthly protocols (Bhaskaran et al., 2019; Shahadat et al., 2022).

Safety Profile, Nanotoxicology, and Quality Control

The administration of any heavy or noble metal to pediatric populations demands rigorous toxicological scrutiny. Because modern regulatory toxicology emphasizes heavy metal limits in food and therapeutics, evaluating the safety profile of *Swarna Bhasma* is essential.

Elemental Gold vs. Chemically Ionic Gold Salts

Much of the clinical wariness regarding gold originates from historical rheumatology, where synthetic **water-soluble ionic gold(I) salts** (e.g., sodium aurothiomalate, auranofin) were used for adult rheumatoid arthritis. These ionic complexes frequently induced dose-dependent nephrotoxicity (membranous glomerulonephritis), cutaneous eruptions, and bone marrow suppression.

Conversely, *Swarna Bhasma* consists of zero-valent, crystalline, water-insoluble metallic gold (Au^0) stabilized in a carbonaceous, organo-mineral matrix (Paul & Sharma, 2011; Saini et al., 2023). Pharmacokinetic studies demonstrate that zero-valent gold nanoparticles do not dissociate into free destructive Au^+ or Au^{3+} cations within the physiological pH range. Instead, they remain chemically unreactive and traverse cellular barriers as colloidal clusters that are gradually cleared by the reticuloendothelial system (Mitra et al., 2002; Saini et al., 2023).

Preclinical Toxicity Assessments

- **Acute and Sub-Acute Toxicity:** Preclinical studies in rodent models (Wistar rats and Swiss albino mice) evaluating *Swarna Bhasma* at doses ranging from 2.5 mg/kg to 50 mg/kg (up to 10 to 50 times the human equivalent pediatric dose) for 28 to 90 continuous days revealed:
    - No observable neurological or behavioral abnormalities.
    - No significant shifts in serum alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), blood urea nitrogen (BUN), or serum creatinine (Mitra et al., 2002; Singhal et al., 2021).
- **Histopathological Evaluation:** Microscopic examination of vital organ sections (lungs, liver, kidneys, spleen, and brain) demonstrated intact alveolar architecture without pulmonary fibrosis, normal hepatic lobular histology without central vein congestion, and normal renal glomeruli and proximal convoluted tubules without hydropic degeneration or metallic crystallization (Singhal et al., 2021; Saini et al., 2023).
- **Genotoxicity:** In vitro Ames tests and chromosomal aberration assays confirmed that certified *Swarna Bhasma* lacks mutagenic, clastogenic, or DNA-damaging properties (Paul & Sharma, 2011).

Regulatory Pitfalls and the Imperative for Standardized Pharmacopoeias

The primary safety risk associated with *Swarna Prashan* does not stem from authentic classical pharmacology, but from substandard, unverified manufacturing:

Incomplete Incineration (*Apakva Bhasma*): Improper heating or abbreviated *Puta* cycles can leave coarse, uncalcined metallic gold or mercury residues from intermediate processing, potentially irritating delicate pediatric renal and gastrointestinal tracts (Khedekar et al., 2016).

Unregulated Folk Practice: The crude domestic practice of scratching modern commercial gold ornaments against rough stones with water must be strictly prohibited. Contemporary commercial gold jewelry contains base-metal alloying components (copper, zinc, nickel, and cadmium) that can cause acute metallic toxicity in infants.

Good Manufacturing Practice (GMP) Adherence: All *Swarna Bhasma* utilized in clinical electuaries must strictly comply with the **Ayurvedic Pharmacopoeia of India (API)** standards. Batch releases must verify negative chemical tests for free gold (*Apunarbhava*), total absence of detectable lead and cadmium via Inductively Coupled Plasma Mass Spectrometry (ICP-MS), and certified sub-micron particulate size distributions via Dynamic Light Scattering.

Comprehensive Clinical Administration Protocol

To bridge traditional canonical wisdom with modern pediatric safety, the following clinical protocol is recommended for pediatric RRTIs:

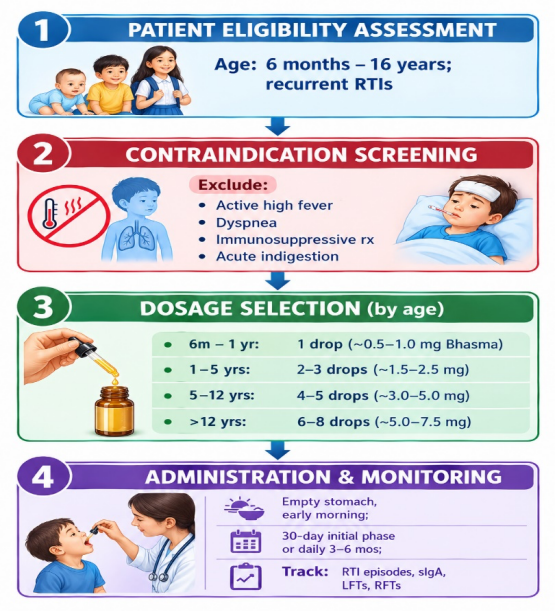


Figure 4. Proposed clinical workflow for Swarna Prashan administration

Clinical Indications

- Pediatric Recurrent Upper Respiratory Tract Infections (rhinopharyngitis, tonsillitis, otitis media).
- Recurrent non-specific bronchitis, wheezing, and post-viral reactive airway dysfunction.
- Failure to thrive secondary to recurrent chronic infections.
- Chronic low *Agnibala* (poor appetite, impaired nutrient absorption, early weight plateaus).

Absolute and Relative Contraindications

- **Acute Febrile Illness (*Taruna Jwara*):** During active systemic viral/bacterial infections, high fevers, or severe acute inflammation, *Rasayana* and heavy electuaries (*Lehana*) are contraindicated. Administering bio-enhancers during acute *Ama* states can exacerbate channel obstruction (Charaka et al., 2011).
- **Acute Gastroenteritis (*Atisara* / *Ajeerna*):** Severe diarrhea, persistent vomiting, or acute metabolic indigestion (*Ama Dosha*).
- **Children on Active Immunosuppressive Therapy:** Post-organ transplant patients or children receiving high-dose systemic corticosteroids or biologicals (due to potential immune-activation interference).
- **Documented Allergies to Apicultural Products:** Known anaphylaxis or severe hypersensitivity to raw honey or royal jelly.

Age-Specific Dosing Framework

6 months – 1 year: 1 drop daily (containing ~0.50–1.0 mg Swarna Bhasma equivalent)

1 year – 5 years: 2 to 3 drops daily (containing ~1.50–2.50 mg Swarna Bhasma equivalent)

5 years – 12 years: 4 to 5 drops daily (containing ~3.00–5.00 mg Swarna Bhasma equivalent)

12 years – 16 years: 6 to 8 drops daily (containing ~5.00–7.50 mg Swarna Bhasma equivalent)

Timing and Anupana

- **Timing of Administration:** Administered strictly in the early morning on an empty stomach (*Pratah Kaal*, *Niranna Avastha*). Fasting preserves a favorable sublingual and gastric absorption window, avoiding food competition. Food intake should be delayed for at least 30 to 45 minutes following ingestion.
- **Duration of Regimen:**
    - *Acute Prophylactic Phase:* 30 consecutive daily doses during seasonal climate transitions (e.g., autumn to winter, or winter to monsoon).
    - *Deep Restorative Phase:* Continuous daily administration for 90 to 180 consecutive days in severe cases of pediatric RRTIs with secondary developmental delays.

Future Directions and Research Roadmap

While contemporary clinical studies and historical usage support the efficacy of *Swarna Prashan*, several scientific imperatives must be addressed to firmly integrate this ancient modality into mainstream integrative pediatrics:

Multicenter Double-Blind Randomized Controlled Trials: Most available studies are limited by small sample sizes, open-label designs, or single-institution settings. Rigorous, double-blind, placebo-controlled trials comparing standardized *Swarna Prashan* against matched honey-ghee vehicles across diverse geographic settings are needed.

Standardization of Molecular Biomarkers: Future clinical protocols should prioritize objective molecular endpoints, including:

- Flow-cytometric profiling of peripheral T-helper subsets (Th1, Th2, Th17, and Treg percentages).
- Quantification of baseline and post-treatment mucosal secretory IgA (sIgA) via ELISA.
- Multiplex serum cytokine arrays (measuring IFN-γ, TNF-α, IL-2, IL-4, IL-6, IL-10, and IL-13).
- Whole-genome transcriptional profiling of airway epithelial cells to reveal gene-regulatory networks affected by gold nanoparticles.

Pharmacokinetics and Biodistribution

Profiling: Longitudinal inductively coupled plasma mass spectrometry (ICP-MS) studies tracing elemental gold biodistribution, clearance kinetics, and biological half-life in human biological fluids will provide precise excretion parameters.

Metagenomic Gut-Lung Axis Analysis: High-throughput 16S rRNA gene sequencing should evaluate how the lipids, honey, and bio-mineral components reshape pediatric gut microbiota, assessing how microbiome changes modulate respiratory immunity.

Conclusion

Pediatric Recurrent Respiratory Tract Infections represent a major public health concern complicated by excessive antibiotic utilization and secondary antimicrobial resistance. *Swarna Prashan*, a foundational formulation of Ayurvedic pediatrics (*Kaumarbhritya*), serves as a multi-target, biomacromolecular-delivery platform that addresses host vulnerability rather than merely suppressing symptoms.

Physicochemical investigations demonstrate that the calcinated gold component (*Swarna Bhasma*) acts as a biologically capped, bio-compatible nanoparticle system dispersed within an emulsified lipid-carbohydrate matrix (*Ghrita* and *Madhu*). Pharmacologically, it modulates the immune response by enhancing respiratory mucosal sIgA secretion, priming macrophage phagocytic responses, balancing CD4+ T helper cell differentiation toward a protective Th1 phenotype, and downregulating damaging inflammatory cytokine pathways.

Clinical trials demonstrate meaningful reductions in RRTI frequency, shortened symptomatic durations, and improved pediatric anthropometric markers without detectable toxicity when prepared under strict pharmacopoeial standards. Implementing standardized manufacturing, validated safety testing, and large-scale multicenter clinical trials will help establish *Swarna Prashan* as a validated, cost-effective, integrative pediatric immunomodulatory strategy.

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