



AN OPEN LABEL SINGLE ARM CLINICAL STUDY TO EVALUATE THE COMBINED EFFICACY OF PHALA GHRITA AND TRIKANTAKADI CHURNA IN THE MANAGEMENT OF KSHEENA SHUKRA VIS-À-VIS OLIGOSPERMIA

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Abstract

Background: *Ksheena Shukra*, one of the *Ashta Shukra Dushti* (eight disorders of semen) described in Ayurveda, is clinically correlated with oligospermia, a major cause of male infertility characterized by a reduced sperm count. Ayurveda advocates a holistic approach to its management by improving both semen quality and reproductive health. This study evaluated the efficacy of *Phala Ghrita* (described in *Ashtanga Hridaya*) and *Trikantakadi Churna* (described in *Vangasena Samhita*) following *Koshta Shuddi* using *Hareetakyadi Yoga*. **Objective:** To assess the therapeutic efficacy of *Phala Ghrita* and *Trikantakadi Churna* after *Koshta Shuddi* in the management of *Ksheena Shukra* (oligospermia). **Methods:** A single-arm, open-label observational clinical study was conducted among 30 married men aged 21–45 years with *Ksheena Shukra* and a sperm count below 15 million/mL. *Koshta Shuddi* was performed using 12 g of *Hareetakyadi Churna* with warm water for up to three days, followed by 12 mL of *Phala Ghrita* and 6 g of *Trikantakadi Churna* administered twice daily with lukewarm milk as *Anupana* for 90 days. Objective parameters were analyzed using the paired Student's *t*-test, and subjective parameters using the Chi-square (χ^2) test. **Results:** Significant improvement was observed in sperm count, which increased from 10.00 to 35.83 million/mL, and semen volume, which increased from 3.32 to 3.62 mL ($p < 0.001$). *Dourbalya* and *Klaibya* also improved significantly ($p < 0.05$), whereas improvement in *Panduta* was not statistically significant ($p > 0.05$). **Conclusion:** The combination of *Phala Ghrita* and *Trikantakadi Churna* following *Koshta Shuddi* appears to be an effective Ayurvedic intervention for improving sperm count, semen volume, and associated clinical features in patients with *Ksheena Shukra* (oligospermia).

Keywords: *Ksheena Shukra*; Oligospermia; *Koshta Shuddi*; *Hareetakyadi Yoga*; *Phala Ghrita*; *Trikantakadi Churna*.

Introduction

In *Ayurveda*, achieving healthy offspring is vital to fulfilling the core tenets of life (*Dharma*, *Artha*, *Kama*, *Moksha*). Parenthood is a highly sought-after goal, and procreative failure causes deep psychological anguish. Conception relies on four essential factors: *Ritu* (reproductive age/ovulation period), *Kshetra* (reproductive tract), *Ambu* (nutritional factors), and *Beeja* (sperm and ovum). Pathological changes in the *Shukra dhatu* (semen/spermatogenic tissue), categorized under *ashta shukra dushti*, directly cause male infertility.

Ksheena Shukra represents a qualitative and quantitative decline of *Shukra*, leading to symptoms like *Dourbalya* (loss of strength), *Sadana* (exhaustion), *Shrama* (tiredness), and *Klaibya* (impotency). In contemporary medicine, this mirrors **Oligospermia**, defined by the World Health Organization (WHO) as a sperm concentration below 15 million/ml. While modern cases often rely on expensive Medical Assisted Reproductive Techniques (MART) like IVF or ICSI, *Ayurveda* utilizes *Vajikarana* (aphrodisiac/virility therapy) to naturally promote spermatogenesis (*Shukrajanana*) and clear sperm abnormalities.

This study tests the clinical hypothesis that combining the systemic rejuvenating properties of *Phala Ghrita* with the potent spermatogenic activity of *Trikantakadi Churna* provides an effective option for oligospermia.



Disease & Review of Literature

Historical Ayurvedic Context

- **Vedic Period^{1,2}:** The foundational roots of *Ayurveda* stem from the *Atharvaveda*. Early texts utilize terms like '*Retas*' and '*Veerya*' to denote male reproductive factors. Early texts emphasize the excellence of the divine physicians, the *Ashwini Kumars*, in treating sterility.
- **Classical Samhitas:** *Ksheena Shukra* is thoroughly institutionalized across major classics:
 - *Charaka Samhita*³ defines its diagnostic symptoms (*lakshanas*) in *Kiyanta Shirasiya Adhyaya* and outlines its etiology under *Shukra Kshaya Hetus*.
 - *Sushruta Samhita*⁴ attributes *Shukra dosha* to the impairment of *Vyana vata* and *Apana vata*, stating that *Upachaya* (nourishment/tissue building) is the main treatment line.
 - *Ashtanga Hridaya*⁵ clarifies that *Ksheena Retas* stems from a combined vitiation of *Vata* and *Pitta* doshas.

Spermatogenesis and Contemporary Factors⁶

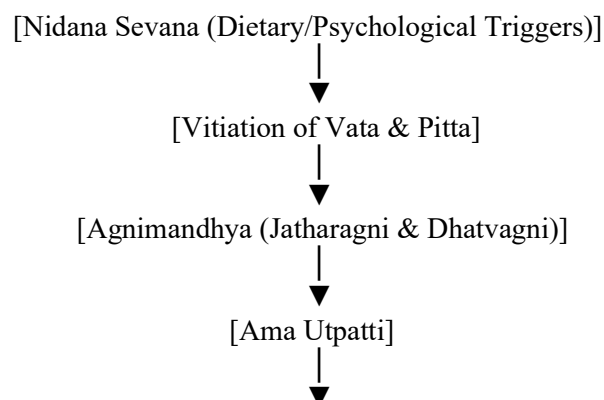
Spermatogenesis is a highly regulated temperature-sensitive process taking place within the seminiferous tubules of the testes, requiring a environment approximately 2°F lower than core body temperature. It is controlled systemically by the hypothalamic-pituitary-gonadal axis via GnRH, FSH, LH, and locally via testosterone secreted by Leydig cells and metabolic support from Sertoli cells.

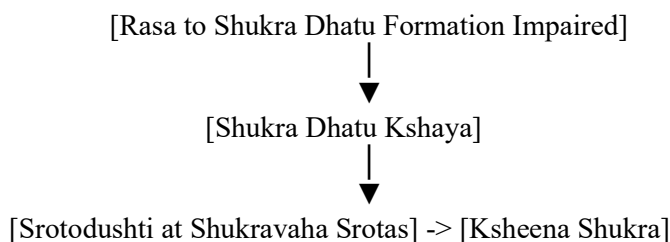
Pathological depletion of sperm concentration (Oligospermia) arises from pre-testicular causes (hormonal imbalances, high stress), testicular causes (varicocele, crypto-orchidism, age, genetic defects), or post-testicular causes (ductal obstructions, genitourinary tract infections). Modern triggers like prolonged sitting, tight undergarments, exposure to laptop/industrial radiation, environmental toxins, and chemical substances (e.g., cimetidine, certain antibiotics) induce oxidative stress through free radicals (*Ama* at the cellular level), damaging sperm DNA and arresting cell maturation.

Ayurvedic Etiopathogenesis (*Samprapti*)

Ksheena Shukra operates via two primary pathways of tissue depletion:

1. **Anuloma Kshaya (Progressive Impairment):** Excessive intake of *Ruksha* (dry), *Ushna* (hot), and *Katu-Amla-Lavana* (pungent, sour, salty) foods impairs *Jatharagni* (core digestive fire)^{7,8}. This leads to metabolic toxins (*Ama*) and *Rasagni mandya*, generating sub-optimal *Rasa Dhatu*. Devoid of accurate nutritional precursor matter, subsequent tissue synthesis declines progressively across the *dhatu* chain, culminating in a depleted *Shukra Dhatu*.
2. **Pratiloma Kshaya (Retrograde Depletion):** Induced directly by behavioral factors like *Ativyavaya* (excessive sexual indulgence) or deep emotional stress (*Chinta*, *Krodha*, *Shoka*). Vitiating *Vata* and *Pitta* deplete *Shukra* directly^{9,10}. Vitiating *Pitta* dries up the unctuous, *Saumya* (cool/water-dominant) nature of semen, while the *Ruksha* quality of *Vata* reduces overall volume and drives delayed ejaculation (*Chirat Praseka*).





Drug Review & Methodology

Composition of Trial Formulations

1. Hareetakyadi Yoga (Koshta Shuddi)^{11,12,13}

Composed of equal parts dry powders of *Haritaki* (*Terminalia chebula*), *Saindhava Lavana* (Rock salt), *Amalaki* (*Emblica officinalis*), *Guda* (Jaggery), *Vacha* (*Acorus calamus*), *Vidanga* (*Emblica ribes*), *Haridra* (*Curcuma longa*), *Pippali* (*Piper nigrum*), and *Shunti* (*Zingiber officinale*). Characterized by *Laghu-Ruksha-Teekshna* qualities, it functions as a *Srotoshodhaka* agent to clear channel obstructions, ignite metabolic fires (*Deepana-Pachana*), and execute metabolic bowel cleansing (*Anulomana*).

2. Trikantakadi Churna (Shamana)

Contains *Kapikacchu* (*Mucuna prurita*), *Gokshura* (*Tribulus terrestris*), and *Shatavari* (*Asparagus racemosus*) blended with *Khanda Sharkara*. It possesses high *Madhura Rasa*, *Madhura Vipaka*, and *Sheeta Veerya*. It acts directly as a *Vrishya* (aphrodisiac) and *Shukrala* (spermatogenic) compound.

3. Phala Ghrita (Shamana)

A lipid-based formulation consisting of multiple herbs processed in *Go-Ghrita* (cow's ghee) and *Go-Ksheera* (cow's milk), including *Manjistha*, *Kustha*, *Tagara*, *Triphala*, *Vacha*, *Haridra*, *Daruharidra*, *Yastimadhu*, *Meda*, *Hingu*, *Katuorhini*, *Kshira Vidhari*, *Kakoli*, *Ashwagandha*, and *Shatavari*. It is specifically indicated for *Shukradoshahara* and *Pumsavanam* actions, pacifying *Vata-Pitta* imbalances and nourishing the deeper *dhatu*¹⁴.

Clinical Trial Design

[35 Subjects Screened] —(5 Discontinued)—> [30 Completed Subjects Monitored]

↓

[Diagnostic Criteria Verification]
Symptoms of Ksheena Shukra & Count <15M/ml

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[Phase 1: Koshta Shuddi (Days 1–3)]
12g Hareetakyadi Churna + Ushna Jala

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[Phase 2: Core Treatment (Days 4–93)]
• 12 ml Phala Ghrita (Twice daily)
• 6g Trikantakadi Churna (Twice daily)
• Vehicle: Sukoshna Ksheera (Warm milk)





[Statistical Testing]

- Objective: Student's Paired t-test
- Subjective: Chi-square (χ^2) Test

- **Inclusion Criteria:** Married male subjects aged 21–45 years presenting clinical symptoms of *Ksheena Shukra* accompanied by an objective baseline semen analysis showing a sperm count $< 15 \text{ million/ml}$.
- **Exclusion Criteria:** Subjects presenting with complete Azoospermia, *Pyospermia* (active genitourinary infection), or comorbid systemic conditions (such as HIV, HBsAg, or Tuberculosis).

Observations & Baseline Profiles

Out of 35 registered subjects, 5 discontinued trial participation, leaving **30 subjects** who completed the full 90-day intervention course.

Demographic & Occupational Data

- **Age Distribution:** The highest incidence was observed in the 31–35 age bracket with 17 subjects (56.66%), followed by 8 subjects (26.66%) in the 26–30 range, and 5 subjects (16.66%) between 36–40 years.
- **Socio-Economic & Diet Profiles:** 12 subjects (40%) belonged to the middle class, 11 (36.66%) to the lower-middle class, and 7 (23.33%) to the upper-middle class. The vast majority (93.33%) consumed a mixed (non-vegetarian) diet.
- **Professional Hazards:** 12 subjects (40%) worked as software engineers, followed by business owners, drivers, and office workers (13.33% each). Sedentary work postures, high mental stress (*Chinta*), and digital screen/laptop exposure were highly prominent among the software engineers.
- **Etiological Findings (*Nidana*):** Dietary evaluation confirmed that 76.66% frequently consumed *Ati Ushna* (excessively hot) and *Ati Katu* (highly pungent) foods, and 70% regularly ate *Ati Ruksha* (dry) foods. Psychological mapping revealed widespread *Chinta* (anxiety/worry) in 73.33% and *Krodha* (anger/stress) in 63.33% of subjects.

Clinical & Physical Paradigms

- **Digestive Capacity (*Agni*):** Baseline mapping showed a high prevalence of metabolic weakness: **60% possessed *Mandagni*** (sluggish digestion), 33.33% had *Vishamagni* (irregular digestion), and 6.66% had *Teekshnagni*.
- **Constitutional Type (*Prakriti*):** 16 subjects (53.33%) presented with a dominant *Vata-Pitta* constitution, confirming a systemic vulnerability to *Shukra-shosho* (fluid depletion).
- **Organ Examinations:** Digital and physical examinations of the penis, scrotum, testes, spermatic cord, epididymis, and vas deferens revealed 100% anatomically normal boundaries across all 30 subjects, ruling out physical structural obstructions or masses.

Results & Statistical Analysis

1. Objective Efficacy Parameters

Quantitative seminal alterations were verified by comparing pre-treatment (BT, Day 1) values against post-treatment (AT, Day 91) records through the Student's paired t-test.

Sperm Count

The expansion of sperm concentration per milliliter was found to be statistically **highly significant** ($p < 0.001$).

- Mean Sperm Count (Before Treatment): **10.00 million/ml**
- Mean Sperm Count (After Treatment): **35.83 million/ml**
- Mean Difference: **$+25.83 \text{ million/ml}$**
- Statistical Test Value: $t = 17.524$

Semen Volume

Ejaculate fluid quantities showed a statistically **highly significant** gain ($p < 0.001$).



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- Mean Semen Volume (Before Treatment): 3.32 ml
- Mean Semen Volume (After Treatment): 3.62 ml
- Statistical Test Value: $t = 4.392$

2. Subjective Efficacy Parameters

Qualitative tracking and symptomatic relief were calculated using the Chi-square (χ^2) test.

Clinical Parameter	Phase	Symptom Present	Symptom Absent	χ^2 Value	p-value	Clinical Significance
Dourbalya (Weakness)	BT (Day 1) AT (Day 91)	20 8	10 32	4.43	< 0.05	Statistically Significant
Klaibya (Erectile Dysfunction)	BT (Day 1) AT (Day 91)	13 3	17 27	3.85	< 0.05	Statistically Significant
Panduta (Paleness)	BT (Day 1) AT (Day 91)	5 1	25 29	0.66	> 0.05	Statistically Non-Significant

Note: Baseline profiles recorded an absolute absence (0%) of Mukhashosha (dry mouth) and Shukra avisargata (complete anejaculation) among the selected 30 subjects.

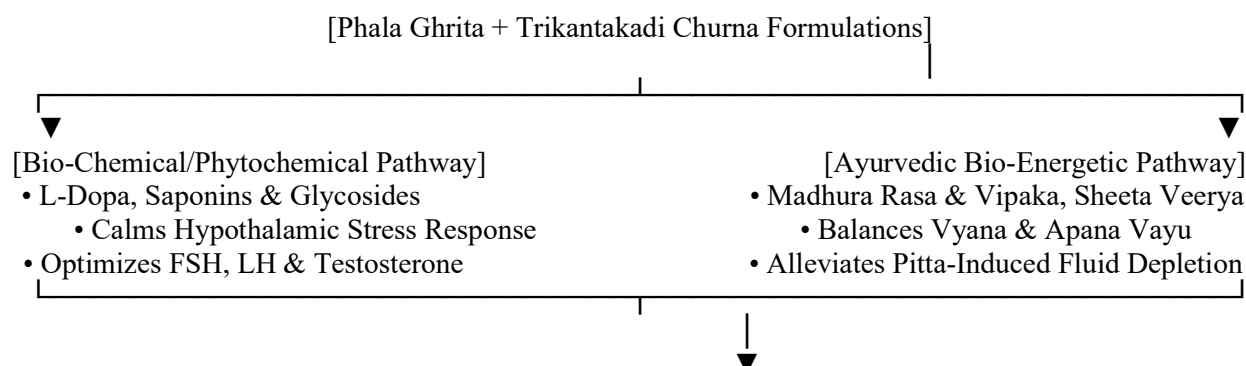
Discussion & Mechanism of Action

Role of Koshta Shuddi via Hareetakyadi Yoga

Administering *Hareetakyadi Yoga* for 3 days successfully regulated *Vatanulomana* (downward movement of Vata) and cleared *srotorodha* (channel micro-obstructions) within the *Rasavaha* and *Shukravaha srotas*. Restoring *Jatharagni* efficiency ensures that the therapeutic ingredients of the subsequently administered *Vajikarana* compounds are fully digested, metabolized, and delivered to the tissue targets.

Spermatogenic Mechanism of Trial Drugs

The therapeutic synergy of *Phala Ghrita* and *Trikantakadi Churna* works through the foundational principle of *Samanya Visheshha Siddhanta* (like increases like). Semen (*Shukra*) is naturally *Saumya* (cool, unctuous, fluid, and sweet). The trial drugs supply matching properties (*Madhura Rasa*, *Madhura Vipaka*, *Snigdha-Guru-Picchila Guna*, and *Sheeta Veerya*), which directly build up the depleted tissue matrix.





[Stimulation of Germ Cell Proliferation & Sertoli Support]



[Highly Significant Quantitative/Qualitative Efficacy]

- Sperm Concentration: +25.83 Million/ml
- Semen Volume & Peripheral Virility Restored

- **Phytochemical Actions:** Herbs such as *Ashwagandha* and *Shatavari* contain steroidal saponins, alkaloids, and key amino acids that stimulate the hypothalamic-pituitary-gonadal axis. This optimizes the release of FSH and LH, prompting Leydig cells to maintain steady testosterone levels and boosting germ-cell proliferation.
- **Stress and Oxidative Control:** *Mucuna prurita* (*Kapikacchu*) is rich in natural **L-Dopa**, which feeds into the brain's dopaminergic pathways to lower stress-induced catecholamine depletion. Acting alongside the antioxidant properties of *Gokshura*, this compound neutralizes free radicals (*Ama*), shielding maturing spermatids from oxidative DNA damage.
- **Seminal Fluid Volume Enhancement:** Semen volume is primarily determined by accessory reproductive gland secretions (prostate and seminal vesicles). The highly significant rise in fluid volume ($p < 0.001$) indicates that *Phala Ghrita* acts directly on these accessory organs to enhance their secretory output.
- **Symptomatic Relief:** The significant reduction in *Dourbalya* and *Klaibya* stems from the formula's *Balya* (strength-promoting), *Brimhana* (nourishing), and *Rasayana* (rejuvenating) traits, which improve vascular flow to the pelvic floor and restore vitality.

Conclusion & Recommendations

- This clinical study proves that combining *Phala Ghrita* and *Trikantakadi Churna* provides significant therapeutic efficacy in managing *Ksheena Shukra* vis-à-vis Oligospermia, validating the alternative hypothesis.
- The intervention significantly increases sperm count and semen volume while relieving physical weakness (*Dourbalya*) and performance issues (*Klaibya*).
- **Future Research Framework:** To build on these findings, future studies should consider expanded, multi-center sample groups, long-term post-trial follow-ups to track pregnancy success rates, and comparative clinical arms to isolate the individual properties of the ghee versus the herbal powder blend.

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