MAHARASHTRA UNIVERSITY OF HEALTH SCIENCES, NASHIK

"COMPARATIVE STUDY OF ASHWAGANDHA GHRUT ORAL YOG & UTTARBASTI IN PCOS."

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Introduction

Polycystic Ovarian Syndrome (PCOS)

- One of the most common endocrinological disorders affecting approximately 20 - 30% of women in reproductive age (12-45 years)
- > One of the leading causes of female infertility (40%).
- Is a heterogeneous disorder presenting with anovulation, irregular mensuration, infertility due to anovulation, polycystic ovaries, excessive amounts of androgenic hormones, insulin resistance offen associated with obesity, type 2 diabetes and high cholesterol level.

Approach to PCOS

- > In modern medicine
 - □ Treatment is mainly hormonal, symptomatic, anti-diabetic, all having adverse side effects.
 - Surgical drilling option or partial oophorectomy is not preferred by most of women.
- Therefore there is wide scope of research to find out safe & potent remedy from Ayurveda for treatment of PCOS. From ayurvedic point of view, there is avarodha of vata because of kapha which in turn affects the follicular growth and release of ovum from ovary.

Importance of Present Study

> Ashwagandha

- Has rasayana property which helps in formation of proper rasa dhatu, as a result its updhatu artava will also be prakuta.
- Is vatanulomak and decreases kapha avarodha.

ASWAGANDHA GHRUT ORAL YOG

□ When ingested, ashwagandha ghrut balances vata & kapha doshas also as it is ghrut shaman of pitta dosha will also take place & thus it will act as tridoshghna. Therefore ashwagandha ghrut oral yog is selected.

Importance of Present Study (Contd.)

- ASHAWAGANDHA GHRUT UTTARBASTI
 - □ Vata dosha is the govering factor of the whole reproductive physiology.
 - PCOS is actually a disease of apan Kshetra.
 - Basti is the best treatment for vata.
 - □ Repeated administration of uttarbasti is the best remedy to treat artava dushti janya vikaras.
 - ☐ Uttarbasti has not been very widely studied in past on PCOS & Ashwangandha ghrut uttarbasti is still untouched.



Aims & Objectives

> Aim

To compare the efficacy of ashwagandha ghrut uttar basti & oral yog in PCOS.

> Objectives

- To study the efficacy of ashwagandha ghrut uttarbasti and oral yog on reduction of ovarian volume.
- To study the efficacy of ashwagandha ghrut uttarbasti and oral yog on quantity of menstrual bleeding.
- To study the efficacy of ashwagandha ghrut uttarbasti and oral yog on regularisation of menstrual cycle.
- □ To study the efficacy of ashwagandha ghrut uttarbasti and oral yog on follicular size.



> Hypothesis

Ashwagandha ghrut oral yog is more effective than ashwagandha ghrut uttarbasti in PCOS.

> Alternate Hypothesis

Ashwagandha ghrut uttarbasti is more effective than ashwagandha ghrut oral yog in PCOS,

> Null Hypothesis

Ashwagandha ghrut uttarbasti & oral yog is equally effective in PCOS



Previous work done

- > MUHS -
- Comparative study of varunadi kwatha with or without madhu tailikbasti in PCOS
- Study of efficacy of maharasnadi kwatha in PCOS (2012-13)
- Efficacy of palashadi basti on PCOS (2012-13)
- Efficacy of kulatha kwatha on Nasthartava w.s.r. PCOS (2011-12)
- □ Comparative study of lasunadi ghrut pana & matra basti on PCOS (2012-13)
- Role of shatapushpadi vati in artavashaya.

Previous work done (Contd.)

- JAMNAGAR -
- Comparative Study of Ashwagandha ghrut and Phala ghrut uttarbasti and oral yog in the management of vandhyatva w.s.r to cervical factor, IPGT; Parikh.P.M, 2001
- Clinical Study on polycystic ovarian disease and its management by Shatapuspha Taila Matrabasti and Pathadi Kwatha IPGT; Krupa Patel 2011
- TRIVANDRUM -
- □ The Study to evaluate the effect of an Ayurvedic Formulation in PCOS, Jose Preethi 2003.
- Management of PCOS w.s.r to Lasuna Rasayana, Uma Venugopal, 2005.
- Clinical Trail to evaluate the efficacy of Palasaksharam with Palasakashayam in the management of PCOS, Jyoti.P.K, 2008.

Materials & Methods

Materials & Methods

Source of data

Review of literature

All the bhrihat trayees & laghu trayees will be reviewed for reference.

Related modern test will be referred

Drug

Ashwagandha ghrut is mentioned in Gadanigraha.

Method of preparation of Ashwagandha Ghrut

- Reference Sharangdhar Samhita/Madhyam Khand/Adhyay 9/1.
- □ The root of ashwagandha would be taken for the preparation of ghrut. The quantity of ghrut would be 4 times the drug and quantity of kashaya would be 4 times the ghrut.

Materials & Methods

Type of study

Comparative parallel randomized prospective clinical study

Study centre

Worli,

OPD & IPD of prasuti tantra & strirog department of M.A.PODAR hospital (Ayurved) Mumbai - 18.

Medium of dissertation

English supported by ayurvedic terminologies in Sanskrit.

Written informed consent

patient

A written consent of all patients included in study will be taken in best language understands.

Ethical clearance

Ethics committee approval will be taken.

Grouping for Clinical Trial

No. of Patients for study will be 60.

Group A - 30 patients will be given Aswagandha Ghrut Oral Yog (Sevnarth)

- Matra 40 ml ghrut OD.
- Time of administration -Morning (Empty Stomach).
- Duration 7 days after ceassation of menses for consecutive 3 cycles
- Anupana Sukhoshna jala.

- Group B 30 patients will be given Aswagandha Ghrut Uttarbasti
- Matra 3 to 5 ml according to individual uterine capacity for 7 days
- Duration 7 days after cessation of menses for consecutive 3 cycles.

Plan of Study

> 30 Patients will be given ashwagandha ghrut oral yog for 7 days and 30 patients will be given ashwagandha ghrut uttarbasti for 7 days after the cessation of menses for 3 consecutive cycles.

- Follow up will be done on day 5 of menses for consecutive 4 cycles.
- Follicular study, USG, Hormonal Profile will be done before treatment and after treatment and results would be compared.



Criteria for Selection of **Patients**

Inclusion Criteria Married patients of age group 18 -

- 45 years.
- Irregular menses and/or scanty menses due to PCOS
- Infertility due to anovulatory cycle due to PCOS.
- > In USG, presence of multiple ovarian follicles less than 12 mm diameter & increased ovarian volume.

Exclusion Criteria Unmarried patients

- Patients of PCOS having malignancies, tuberculosis, DM, Hypothyroidism, HIV, HBsAg, VDRL
- Pregnancy
- Cervical tumour, polyp
- Uterine fibroid
- Congenital anomalies in female genital tract.

Investigations

- USG (Pelvis) before & after treatment for follicular size, ovarian volume.
- Follicular study before and after treatment it will be done from 10th day of menstrual cycle up to at least 22nd day of cycle to see ovulation or anovulation
- Hormonal profile (FSH, LH, PRL, TSH) on Day 2/3 of menses, before after treatment.
- > Serum insulin
- All routine haematological investigations CBC, ESR, Blood Group, HIV, HBsAg, VDRL, Urine (Routine & Microscopic). BSL (Fasting & PP), LFT, RFT

CRITERIA OF ASSESSMENT

Subjective Criteria

Quantity of Bleeding

Grade	Amount of Bleeding		
0	Spotting		
1	Scanty	1 - 2 pads / day	
2	Moderate	2 - 3 pads / day	
3	Excessive	4 - 5 pads / day or more	

Interval of Menses

Grade	Duration in Days
0	28 days
1	28-45 days
2	45-60 days
3	More than 60 days

Objective Criteria

Follicular size

Grade	Follicular size
0	< 12 mm
1	12-20 mm
2	> 20 mm
3	Ovulated

Hormonal Profile

	Before Treatment	After Treatment
1) FSH		11-71111-111
2) LH		
3) PRL		
4) TSH		

Ovarian volume

Ovarian volume	Before Treatment	After Treatment

Statistical Tests

- Unpaired t tests will be applied to compare the parametric data between the groups
- Mann Whitney's test will be applied to compare the non-parametric data between the groups.
- > Paired t test will be applied to compare the parametric data within the group
- Wilcoxon match pair test will be applied to compare the non-parametric data within the group.

Level of significance will be determined as P < 0.05

> Observation

After giving treatment symptoms will be observed and statistical analysis will be done by applying appropriate statistical tests.

> Discussion

The observation and result obtained will be analysed, compared with the present knowledge in the dissertation.

> Conclusion

Conclusion will be drawn based upon assessment of observation table of data and statistical analysis.

> Summary

Based on the criteria mentioned before, study will be conducted & observations & results will be discussed in dissertation.



Follow up Chart

Sr. No.	Name of Criteria	Before T/t	After T/t
1)	Follicular size		
	1. Lt. Ovary		
	2. Rt. Ovary		
2)	Ovarian volume		
3)	Menstrual Bleeding		
4)	Interval of menses		
5)	Hormonal Profile		
a.	FSH		
b.	LH		
C.	PRL		
d.	TSH		

References

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Thank you!