

How to Cite:

Yende, M., Pradnya, D., Preeti, D., Sheetal, T., & Kalpana, T. (2022). Effect of phala ghrita on development of ovarian follicle followed by beejotsarga (ovulation) in patients of infertility due to ovarian factor in comparison with clomiphene citrate. *International Journal of Health Sciences*, 6(S2), 956–967. <https://doi.org/10.53730/ijhs.v6nS2.5060>

Effect of Phala Ghrita on Development of Ovarian Follicle Followed by Beejotsarga (Ovulation) in Patients of Infertility Due to Ovarian Factor in Comparison with Clomiphene Citrate

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Abstract---Background -Failure to ovulate is the major problem in approximately 30% - 40 %cases of female infertility. The Beeja is the core stone of the female reproductive process and absence of this factor Garbha cannot occur in spite of the proper Ritu, Kshetra and Ambu. Vagbhat stated the effect of Phalaghrita on Vandhyatva (infertility), so with an objective to study the effect of Phalaghrita in comparison with clomiphene citrate study will be carried out. Materials and methods-This Single blind(participant) randomized control clinical involves two groups with 30 subjects each. Group A (Study Group)will be treated with administration of Phala Ghritain the dose of 10 ml B.D. orally with Anupana of cow milk 100 ml. Group B

(Control Group) will be treated with administration of Tab. Clomiphene citrate 50 mg O.D. orally for 5 days from day 3 to 7 of Menstrual cycle. Expected outcome - Primary outcome of study will be development of follicle and Beejotsarga (ovulation) and Secondary outcome will be conception. Conclusion- Effect of drug Phala Ghrita will be stated as per observed result.

Keywords---beejotsarga, clomiphene citrate, infertility, ovarian follicle, ovulation, phala ghrita.

Introduction

According to Indian culture marriages are a religious ritual necessary to each individual for completion of the life cycle to complete "Purusharth Chatushtaya". Healthy progeny is the focal aim of marriages. Four vital factors are essential for formation of Garbha i.e. Ritu, Kshetra, Ambu, and Beeja.¹ The union of Beeja of the both sides i.e. Shukra and Artava (ovum) with Atma inside the Kukshi is called Garbha.² The Beeja is the fundamental part of the female reproductive process. Formation of Beeja takes place in ovary, so normalcy of ovary is important for Garbhadhan (Conception). Hence exploration of applied aspects of ovarian dysfunction is important along with Anatomical and Physiological aspects.

In Ayurvedic texts Beejotsarga (ovulation) process is elaborated. Vayu (Vata Dosha), Karma (deeds) and Swabhava (nature) are accountable for folliculogenesis as well as ovulation.³ Ayurveda termed female infertility as Vandhyatva. Failure to achieve conception by a mature aged couple, having normal coitus during suitable period of menstrual cycle, on regular basis, for period of at least for one year is termed as infertility.⁴ Sushruta labelled Vandhyatva under Vandhya Yonivyapada.⁵ Harita cited six types of Vandhya with specific etiology for each with its prognosis.⁶ Vagbhata mentioned different causes specially Abeejatva as a factor responsible for female infertility.^{7,8} Charaka in Sharir Sthana and Chikitsa Sthana has mentioned causes for Vandhyatva.^{9, 10} Kashyap under chapter Revati Jataharni mentioned 'Pushpaghni' which can be co-related with anovulatory cause of infertility with obesity and hirsutism.¹¹ In Madhava Nidana types of Vandhyatva has been described.¹² Bhela has mentioned causes for Vandhyatva and classified it under Vata Vyadhis.¹³ Considering all the references, Revati Jataharini (Pushpaghni), Astaartava Dusti, Yonivyapada, Agnimandya, vitiation of Vata, Strotorodha, Avarana, Dhatuksaya are contributory aspects of Infertility due to Ovarian factors.¹⁴

As per National Health Portal of India, 15% of reproductive-aged couples affected by infertility worldwide. World Health Organization estimated 3.9 to 16.8% of overall prevalence of primary infertility in India.¹⁵ The failure to ovulate is the major problem in approximately 30% - 40% cases of female infertility.¹⁶ This can be anovulation or severe oligo-ovulation. In the cases of oligo-ovulation even though the ovulation does occur, its irregular frequency decreases the chances of pregnancy. The ovarian dysfunction spectrum also includes development failure of an adequately functioning corpus luteum subsequent to ovulation. Hence females with issues of infertility need an immediate attention; especially with ovarian

factor induced infertility. Effective treatment for infertility due to anovulation is found in modern medicine, but its side effects give worry in later stage. For induction of ovulation, hormonal based medicines are the drug of choice. Clomiphene citrate has risen as drug of choice in the induction of ovulation in the female. It is synthetic nonsteroidal triphenylethylene derivative. Alike other selective estrogen receptor modulators example, tamoxifen, it shows both estrogen agonist and antagonist properties, depending on the prevailing endogenous estrogen levels. Clomiphene citrate acts as estrogen agonist when extremely low endogenous estrogen levels otherwise, it acts as antiestrogen¹⁷. It is seen very effective in many patients but still it causes various side effects like ovarian hyper stimulation, menstrual irregularity etc¹⁸.

Ayurveda supported variety of herbo mineral medication, which may provide good results on these issues without any adverse effects. While thinking about applied aspect of Rachana Sharir in the context of female reproductive system, ovarian defects come in the priority area. Phala Ghrita is very popular classical formulation indicated in problems related to conception and infertility due to various causes. It is used for various Yonivyapats, infertility, Graharoga also having Medhya, Balya, Dehavardhan, properties. It is one of the most commonly prescribed classical Ayurvedic formulation for reproductive problems. Sharangadhara, Vagbhata, Yogratnakar and Bhavprakash mentioned Phalagritha in treatment of Vandhyattva. According to Vagbhata, Phalasarpī Phalagritha (which comprises Kalka of Manjishta, Kushtha, Tagara, Amalaki, Haritaki, Vibhitaki, Vacha, Haridra, Daruharidra, Madhuka, Deepyaka, Katurohini, Payasya, Hingu, Musali, Vajigandha and Shatavari, each taken in equal quantity). The ghee was prepared by adding ghee, milk and sugarto the Kalka as per Snehapakamethod¹⁹. Various research works were done to evaluate the efficacy of Phala Ghrita administered in the cases of infertility²⁰. Phala Ghrita was found effective on infertility especially infertility due to cervical²¹ and uterine factors²² through oral and intra uterine route. Whereas no studies were carried out to find out its role in development of follicle and Beejotsarga (ovulation) in the cases with un-ovulatory cycles. Thus, considerable knowledge gap exists regarding the mode of action of Phala Ghrita, especially its role on structural development of follicle and functional development of female reproductive system in terms of Beejotsarga (ovulation) in anovulatory/Oligo ovulatory cycle. Hence present study is proposed to evaluate the development of follicle followed by Beejotsarga (ovulation) through treatment of Phala Ghrita in comparison with Clomiphene Citrate in patients of infertility due to ovarian factor induced.

Table 1
Properties of ingredients of Phala Ghrita

Sr	Drug	Part used	Rasa	Guna	Virya	Vipaka	Dosha-ghnata	Karma
1	Manjistha (<i>Rubia Cordifolia</i>)	bark	Tikta Kashay Madhura	Guru Ruksha	Ushna	Katu	KaphaPitta	JwaraVarnyakara , VishagnaYonivikar, Kushtha
2	Kushtha (<i>Saussurealappa</i>).	root	Tikta, Katu, Madhura	Laghu , Raksha, Tikshna	Ushna	Katu	VataKapha	Analomana, Vrushya, Artavajanana, Garbhashayottejaka

3	Tagar (<i>Valeriana Officinalis</i>)	roots	Tikta, Katu, Kashay	Laghu snigdha	Ushana	Katu	Kapha Vata	Deepan Pachan shulahara, JwaraVatavyadhi
4	Haritaki(<i>Terminalia chebbula</i>)	Fruit	Pancha- rasa	Guru, Snigdha	Sheeta	Madhura	PittaVata	Anulomana, Vrushya, Garbhashayashothahara
5	Bibhitaki(<i>Terminalia bellerica</i>)	Fruit	Kashaya.	Ruksha, Laghu	ushna	Madhura	Tridosha	Garbhasthapana Shothahar, AnulomanKrimighna, Dhatuvardhaka
6	Amalaki (<i>Emblia officinalis</i>)	Fruit	Pancha- rasa.	Guru, Ruksha, Sheeta	Sheeta	Madhura	Tridosha	Dipana, Vrushya, Anulomana
7	Haridra (<i>Curcuma longa</i>)	Rhizo me	Tikta, Katu,	LaghuR uksha,	Ushna	Katu	Tridosha	,Garbhasthapana, Anulomana, Garbhashaya, shodhana,
8	Daruharidra(<i>Berberis aristate</i>)	Stem, Root	Tikta, Kashaya	Ruksha, Laghu	Ushna	Katu	PittaKapha	Dipana, Garbhashayasothahara.
9	Vacha (<i>Acorus calamus</i>)	Rhizo me	Tikta, Katu	Laghu, Tikshna	Ushna	Katu	Kapha, Vata	Krimighna, Vamak, Garbhashaya sankochaka.
10	Yastimadhu(<i>Glycyrrhiza glabra</i>)	Root	Madhur	Guru, Singdha	Sheeta	Madhura	Vata , Pitta	Kandughna, Rasayana, Shukrala, Vajikara
11	Meda(<i>Polygonatum cirrhifolium</i>)	Root	Madhur	Guru	Sheeta	Madhur	Vata, Pitta	Shukral, Balya, Rasayana, Jivaniya
12	Dipyaka (<i>Trachyspermum oxburghianum</i>)	Fruits	Tikta Katu, Tikta	Laghu, Ruksha, Tikshan a	Sheeta	Madhura	Kapha , Vata	Dipana Vatnulomana, Krimighna
13	Katuohini(<i>Picrorhiza kurroa</i>)	Root	Tikta	LaghuR uksha,	Sheeta	Katu	Kapha, Pitta	Krimighna, Shothahara, Dipana.
14	Payasya (<i>Ipomea mauritanica</i>)	tubor	Madhur Tikta	Guru Snigdha	Sheeta	Madhur	Vata, Pitta	VajikarShukral, Balya,
15	Hingu (<i>Ferulananthe</i>)x	Resin	Katu	Laghu Snigdha	Ushna	Katu	Kapha, Vata	Dipana, Pachana, Anulomana, Krimighna.
16	Kakoli (<i>Roscoeaprocera</i>)	Root	Madhur Tikta	Guru Snigdha	Sheeta	Madhur	Vata, Pitta	JivaniyaRasayan, Balya,
17	Ashwagandha(<i>Withania Somnifera</i>)	Root	Tikta, Katu, Kashaya	Laghu, Snigdha	Ushna	Madhura	Kapha, Vata	Rasayana, Garbhashaya , Vajikarana
18	Shatavari(<i>Asparagus racemosus</i>)s	Kanda	Tikta, Madhura	Guru , Snigdha	Sheeta	Madhura	Vata, Pitta	Shukral, Balya, Rasayana, Garbhaposhaka
19	Kshira		Madhura	Guru, Snigdha	Sheeta	Madhura	Vata , Pitta	Jivaniya, Rasayana
20	Ghrita		Madhura	Snigdha , Mrudu	Sheeta	Madhura	Vata , Pitta	Dipana, Vrushya, Vayastha, Medhya.

Aim and objectives

Aim: Evaluation of developmental changes in ovarian follicle followed by Beejotsarga (ovulation) through treatment of Phala Ghrita in comparison with Clomiphene citrate in the patients of infertility due to ovarian factor.

Primary Objectives

- To assess developmental changes in ovarian follicle followed by Beejotsarga (ovulation) through treatment of Phala Ghrita.

- To assess developmental changes in ovarian follicle followed by Beejotsarga (ovulation) through treatment of clomiphene citrate.
- To compare the efficacy of Phala Ghrita and Clomiphene citrate on developmental changes in ovarian follicle followed by Beejotsarga (ovulation).

Secondary Objectives

- To access the effectivity of both drugs on secondary outcome i.e. conception
- To evaluate the effect on of both drugs menstrual abnormalities if any
- To analyze effects of both drugs in the context of different Deha Prakruti

Material and Methods

Study Design -This study will be single blind(participant) randomized control clinical trial in which sample will be collected with computer generated Simple Random method. Study involves two groups with 30 patients in each group. Group A (Study Group) will be treated with Phala Ghrita orally and Group B (Control Group) will be treated with Tab. Clomiphene citrate.

Outcomes: Primary – Development of follicle and Beejotsarga (Ovulation), Secondary – Conception

Source of Data

Subjects will be collected from approved centers by D.M.I.M.S. (D.U.), Wardha. Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H). Sample size was calculated by software n Master 2.0 by which total 60 subjects will be enrolled considering 10% drop out rate and distributed evenly into two groups by random sampling. The groups will be as follows.

- Group A - study group with 30 patients –Phala Ghrita treatment
- Group B - control group with 30 patients –Clomiphene citrate treatment

Intervention and Grouping

- Group A (Study Group):
Treated with Phala Ghrita
Route -Oral
Dose -10 ml B.D.
Anupana –Cow milk 100 ml
- Group B (Control Group):
Treated with Tab Clomiphene citrate
Route -Oral
Dose –50 mg O.D. for 5 days from day 3 to 7 of Menstrual cycle
Anupana –Plane Water

Inclusion criteria

- Females having active married life and unable to conceive from 1 year.

- Patients with primary or secondary Infertility due to ovarian factors
- Irregular or scanty menses due to anovulatory cycle
- Unruptured ovarian follicle

Exclusion criteria

- Females less than 18 years and non-fertile age group patients
- Infertility other than ovarian causes e.g. cervical, uterine causes.
- Congenital anomalies in female genital tract
- Known Tubercular endometritis, Malignant and cytotoxic patients
- Non-Cooperative patients

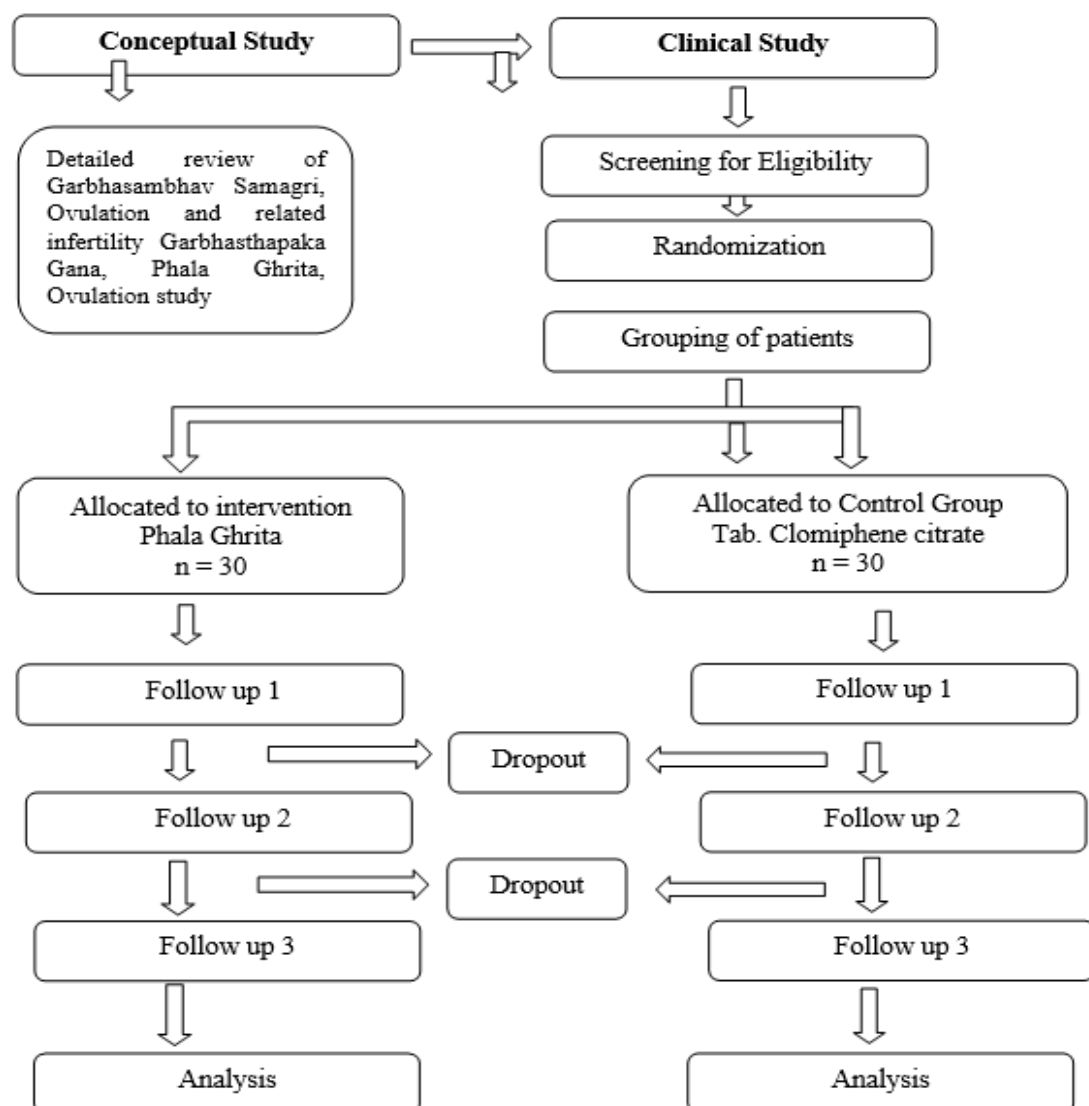


Figure 1. Plan of work

Table 2
Details of method and experimental design

Heading	Group A (Study Group)	Group B (Control Group)
Sample size	30	30
Intervention	Phala Ghrita	Tablet Clomiphene citrate
Dose	10 ml B. D. ²³	50 mg O. D. for 5 days ^{24,25}
Anupan	100 ml Cow Milk	Water
Duration of Intervention	60 days	5 days/cycle- started from day 3 – 7 of menstrual cycle up to 2 cycles.
Follow up	Cycle- 1 TVS from day 10* Cycle- 2 TVS from day 10* Cycle- 3 TVS from day 10* Post Test Sampling	Cycle- 1 TVS from day 10* Cycle- 2 TVS from day 10* Cycle- 3 TVS from day 10* Post Test Sampling
Total trial duration	90 days	90 days
* - as per Transe Vaginal Sonography Protocol		

Preparation of trail drug

- All the raw ingredients will be collected and authentication will be done at Department of Dravyaguna, M.G. A. C. Salod, Wardha
- Phala Ghrita will be prepared according to textual reference of Ashtanga Sangraha Uttara 38/110-111 in the Pharmacy of M. G. A. C. Salod, Wardha. Prepared Ghrita will be package in PET jars with quantity of 300 gm.
- Prepared product will be standardized at Central Laboratory of M. G. A. C., Salod, Wardha.

Control drug

Tablet clomiphene citrate – 50 mg of reputed brand will be dispensed to patients under guidance of department of Gynecology.

Detailed plan of treatment

- Already diagnosed/patients coming to O.P.D. with the complaints of anovulation/ infertility due to Ovarian factors / referred from other centers as per selection criteria will be selected for screening after written consent.
- Screening- Trans vaginal Sonography (T.V.S.) will be done from day 10th of menstrual cycle up to at least 20th day of cycle to diagnose status of ovulation.
- After confirmation of diagnosis grouping of patients will be done as per computerized randomization and treatment will be started.
- Patient will be called for T.V.S. from 10th day of Menstrual cycle as per TVS protocol by sonologist.
- Oral administration of drugs will be given up to maximum 60 days or conception.

- Group A (Study Group) will be treated with 'Phala Ghrita' in the dose of 10 ml B.D. with 100 ml lukewarm cow milk preferably empty stomach
- Group B (Control Group) will be treated with tablet Clomiphene citrate in the dose of 50 mg O.D. at morning for 5 days from day 3 to 7 of menstrual cycle
- T.V.S. will be carried out for Consecutive 2 cycles during trials and 1 cycle after completion of trial or conception.

Screening parameters

- Trans Vaginal Sonography (B.T. & A.T.) for the ovulation study.
(Trans vaginal Sonography will be done from day 10th of menstrual cycle up to at least 20th day of cycle to diagnose status of ovulation. T.V.S. will be carried out Consecutive 2 cycles during trials and 1 cycle after completion of trials.)
- Hormonal assay – FSH, LH, TSH, PRL

Subjective parameters

Table 3
Frequency of menses

Type	Grade
Regular (Cycle of 21 to 35 Days)	0
Irregular (Cycle of <21 to >35 Days)	1

Table 4
Bleeding quantity

Amount of bleeding	Grade
Spotting	0
scanty 1 to 2 pads/day	1
moderate 2 to 3 pads/day	2
excessive 4 to 5 pads/day	3

Table 5
Duration of Bleeding

Type	Days	Grade
Alpartava	1 or <1 day	3
	2 days	2
	3 days	1
Normal	4 – 7 days	0
Atyartava	8 days	1
	9 days	2
	10 or > 10 days	3

Nature

Menstrual pain will be assessed by VAS scale

Objective parameters

Table 6
Size of Follicle

Grade	Follicle size
0	0 - 12 mm
1	12- 18 mm
2	19 - 23 mm
3	Ovulated

Table 7
Thickness of endometrium

Grade	thickness of endometrium
0	<5 mm
1	5-7 mm
2	7-9 mm
3	>9 mm

Assessment of total effect of the therapy

Table 8
The effect of therapy will be assessed as below²⁶

1	Complete Remission	If ovulation occurs it will be considered as complete remission OR patient get conceived
2	Markedly Improved	Improvement in size of follicle up to fully mature size i.e.up to 19-23 mm size will be considered as markedly improved
3	Moderately Improved	Improvement in the size of follicle i.e.12-18 mm will be considered as Moderately improved.
4	Not Improved	No improvement in the size of follicle i. e. less than 12 mm will be considered as Not improved.
	Secondary outcome:	Conception

Analysis plan (Statistical test)

- Interim analysis will be done.
- I.T.T.
- Statistical assessment will be done through paired t test and unpaired test

Outcome

- Primary –Development of follicle and Beejotsarga (Ovulation)
- Secondary - Conception

Discussion

This study may contribute as effective treatment in the cases of ovarian failure as easy and safe therapy. This study can create wide scope to promote Ayurveda in flourishing infertility clinic sector. If the effectiveness of trial drug is proved as a management of ovarian failure, then it will prove great hope for childless couples suffering due to this problem. This will set a standard treatment for induction of ovulation. If trial drug is proved effective, it can be used as alternative treatment in management of infertility due to abnormal development of ovum and ovulation. This study may contribute as alternate treatment for induction of ovulation. This study may also useful for females having risk factors of ovulation related infertility^{27,28}. Further researches of present drug can be carried out for various other causes of infertility.

Conclusion

This study can be used as alternative treatment in management of infertility due to abnormal development of ovum and ovulation. This study will contribute as alternate treatment for induction of ovulation. This study will also useful for females having risk factors of ovulation related infertility as a preventive measure.

Type of Article – Study Protocol

I.E.C. approval Letter no. – MGACHRC/IEC/October-2020/152 Dated 10/10/2020

Ph.D. Registration Letter no. – DMIMS(DU)/PhD Regn/2020/538 Dated 10.10.2020

Conflict of Interest – None

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