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Efficacy of Ferrum metallicum 30C in restoring menstrual cycle in polycystic ovarian syndrome patients – A randomised, placebo-controlled, single-blind trial

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Abstract

Background: Polycystic ovarian syndrome (PCOS) is the most common endocrine disorder affecting women of reproductive age, with the prevalent clinical symptom of irregular menstruation.

Objective: This trial assessed the efficacy of *Ferr. met.* 30C in restoring the menstrual cycle among PCOS patients.

Methods: A randomised, placebo-controlled, single-blind trial was conducted at outpatient departments of Sri Sai Ram Homoeopathy Medical College and Research Centre, Chennai. Patients were randomly allotted to the experimental (Group I - *Ferr. met.* 30C) and control (Group II - Placebo) groups. Quality of life of patients in both groups was assessed through PCOS Questionnaire scale at baseline and at 6th month.

Results: Sixty-five patients were enrolled and randomly assigned to Group I (n = 33) and Group II (n = 32). The menstrual cycle got regularised in 48% of Group I patients and 29% of Group II. Data were also compared to see the menstrual restoration period in both the groups. About 48% of participants in group I and 29% in group II had their menses restored after homoeopathic intervention and the difference between the groups was found to be 1.81 ($p < 0.05$). Improvement in menstrual cycle before and after intervention for patients in both groups showed a significant difference after the intervention (higher in Group I than Group II), confirming the efficacy of intervention in the experimental group: $p < 0.05$.

Conclusion: This trial suggests that *Ferr. met.* 30C could be effective in restoring the menstrual cycle in PCOS patients. Rigorous trials and independent replications are warranted.

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Original Article

Efficacy of *Ferrum metallicum* 30C in restoring menstrual cycle in polycystic ovarian syndrome patients – A randomised, placebo-controlled, single-blind trial

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Abstract

Background: Polycystic ovarian syndrome (PCOS) is the most common endocrine disorder affecting women of reproductive age, with the prevalent clinical symptom of irregular menstruation. **Objective:** This trial assessed the efficacy of *Ferr. met.* 30C in restoring the menstrual cycle among PCOS patients. **Methods:** A randomised, placebo-controlled, single-blind trial was conducted at outpatient departments of Sri Sai Ram Homoeopathy Medical College and Research Centre, Chennai. Patients were randomly allotted to the experimental (Group I - *Ferr. met*. 30C) and control (Group II - Placebo) groups. Quality of life of patients in both groups was assessed through PCOS Questionnaire scale at baseline and at 6th month. **Results:** Sixty-five patients were enrolled and randomly assigned to Group I (n = 33) and Group II (n = 32). The menstrual cycle got regularised in 48% of Group I patients and 29% of Group II. Data were also compared to see the menstrual restoration period in both the groups. About 48% of participants in group I and 29% in group II had their menses restored after homoeopathic intervention and the difference between the groups was found to be 1.81 ($p < 0.05$). Improvement in menstrual cycle before and after intervention for patients in both groups showed a significant difference after the intervention (higher in Group I than Group II), confirming the efficacy of intervention in the experimental group: $p < 0.05$. **Conclusion:** This trial suggests that *Ferr. met*. 30C could be effective in restoring the menstrual cycle in PCOS patients. Rigorous trials and independent replications are warranted.

Keywords: *Ferrum metallicum*, Homoeopathy, Menstrual irregularities, Polycystic ovarian syndrome (PCOS), Polycystic ovarian syndrome questionnaire, RCT.

Introduction

Polycystic ovarian syndrome (PCOS) is a heterogeneous, multisystem endocrinopathy in women of reproductive age.[1] Globally, the prevalence of PCOS is estimated to be between 5.5% and 12.6% in women in the age group of 17–45 years. In India, the prevalence of PCOS is estimated to be between 8.2% and 22.5%.[2] On an average, PCOS affects about one in fifteen women.[3]

PCOS is characterised by infertility, hirsutism, obesity and enlarged ovaries.[4] Menstrual irregularity, a common feature of PCOS, where menses occur at intervals of >6–8 weeks in absence of thyroid, adrenal or other pituitary dysfunctions and is often the earliest clinical manifestation.[5] Polycystic morphology is seen on ultrasound in approximately 22% women.[6]

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Ferr. met., prepared from the fine powder of iron, is often a useful remedy for delayed[7] and suppressed menses.[8] Irregular menstrual flow and great pallor are among the important indications of this remedy.[9] Menses are either too late and too scanty, with pale, watery discharge or long-lasting and profuse.[7]

In the personalised care provided to PCOS patients in a homoeopathic outpatient department (OPD) setting,

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the authors observed that *Ferrum metallicum* 30C was effective in restoring menses in these PCOS patients. In the homoeopathic repertories such as Synthesis,[10] Complete,[11] and Homoeopathic Medical Repertory,[12] *Ferr. met.* has been listed for menses: absent, irregular and intermittent, matching the symptomatology of PCOS. There has not been a pertinent study done before with special focus on observing the role of *Ferrum metallicum* in regulating or improving menses in PCOS patients. Hence, this study aimed to assess the efficacy of *Ferr. met*. 30C in restoring the menstrual cycle in patients suffering from PCOS.

Methods

Study design

This was a prospective, randomised, placebo-controlled, single-blind clinical trial conducted at OPD and peripheral OPD of Sri Sai Ram Homoeopathy Medical College and Research Centre (SSRHMC&RC), Chennai, for 18 months (1 year for enrolment and 6 months for follow-up) between June 2017 and December 2018. The sampling method used was convenient sampling, and the allocation ratio was 1:1. The ethical clearance was obtained from the Institutional Ethical Committee (I.E.C.) of Homoeopathy University, Jaipur, (HU/2016/1301/A, dated 03/08/2016) before the initiation of the study. However, the trial was not registered in Clinical Trials Registry- India (CTRI).

Participants

The women aged between 15 and 35 years, who attended OPD and peripheral OPD of SSRHMC&RC, Chennai, suffering from amenorrhoea or menstrual irregularities with an ultrasonographic diagnosis of PCOS, without fixing any specific duration of the complaint and willing to participate in the study, were included on consent, or assent, as the case was.

The women who reported of secondary amenorrhoea of known aetiology, such as anaemia, thyroid disorders, uterine pathology, diabetes mellitus, Cushing's disease, hyper-prolactinemia, or congenital abnormalities; pregnant and lactating mothers; those taking birth control pills or hormone therapies; those taking regular medication for any other chronic disease; and those unable to participate or unwilling to give informed consent were excluded from the study.

Sample size

Out of 110 patients screened by the principal investigator, 65 patients were enrolled using convenient sampling method.

Randomisation

This is a single-blind, randomised controlled trial, and the participants were assigned to the experimental and control groups by the principal investigator using the simple randomisation method through the drawing lot mechanism. The participants were sequentially asked to pick hidden paper lots numbered as 1 and 2. Based on the numbers they picked, they were allocated to either group I or group II.

Allocation

The enrolled 65 participants were randomly allocated into two groups. Thirty-three participants were placed in *Group I* (Experimental Group - *Ferr. met*. 30C) and 32 participants were placed in *Group II* (Control Group - Placebo).

Blinding

This was a single blind trial where the patients were unaware about the group assigned to them.

Intervention

Patients under Group I (Experimental) were given seven doses of *Ferr. met*. 30C (4 medicated 30 size globules dispensed along with sugar of milk constituted a dose). The sugar of milk was used for dispensing since it is known to be absorbed easily by the body, making it an effective medium for delivering the homoeopathic remedy. It allows for controlled, slow release of the remedy when taken orally, thus facilitating its interaction with the body. The patients in Group II (Placebo/Control) were given seven doses of placebo (identical as experimental group, 4 unmedicated, 30 size globules dispensed along with sugar of milk constitute a dose) every morning for seven consecutive days. The patients were advised to come for the second visit after 15 days or after reappearance of the menses, whichever was earlier. The patients were then followed up monthly from the third visit onwards to know about their regularity in the cycle, and if the cycle was delayed, seven doses of *Ferr. met*. 30C or Placebo were repeated. No supplements were neither advised nor taken by the participants. Each patient was followed up for a period of at least six months.

Outcome measures

The primary outcome was to restore the menstrual cycle in PCOS patients, while the secondary outcome was to assess the improvement in the quality of life of the patient, using the PCOS Questionnaire (PCOSQ) scale. The health-related quality of life questionnaire for women with PCOS[13] was used for the assessment of patients, which consists of 26 questions that explored the impact of PCOS in their quality of life in five domains: body hair, emotions, infertility, weight, and menstrual problems. Each item asked in the PCOSQ is associated with a 7-point scale (1–7) with a range from maximum impairment of HRQL - 1, to no problem or difficulty - 7. Higher scores on the PCOSQ indicate higher functioning.[13] The evaluation of quality of life through PCOSQ was done at baseline and repeated in the sixth month, and the improvement was assessed.

Statistical analysis

The primary outcomes were assessed based on duration of restoration of menstrual cycle between experimental and control groups and secondary outcome (quality of life) was assessed using scores of PCOSQ. The data analysis basically included two types of comparisons: (a) before treatment and after treatment scores and (b) experimental group and control group scores.

The statistical analysis was done using © *Jamovi* (version 2.3) and © SPSS (version 21.02). The change in PCOSQ from baseline to end was compared between groups using independent sample's t-test after confirming the normality of the data using Shapiro–Wilks test. The Chi-square test was used for the comparison of menstruation status in two groups. The odds ratio and effect size (Cohen's d) were calculated. Values are expressed as the mean ± SD. An independent t-test was conducted. The probability value *(p)* was considered statistically significant at <0.05.

Results

Out of 110 patients screened for PCOS, 65 were enrolled and 45 patients were excluded [Figure 1]. Twelve patients (five in the experimental group and seven in the control group) had to be discontinued from the study due to non-compliance to the treatment or follow-ups. Among these, four patients were intervened with hormone therapies (one patient in experimental group and three patients in control group) and the rest of them (four patients experimental group and four patients in control group) were not regular in their visits. Seven patients (three patients in experimental group and four patients in control group) were lost to the follow-ups.

Demographic data

In Group I (Experimental), 21 patients (64%) were between the age group of 16–25 years and 12 patients (36%) were between the age group of 26–35 years. In Group II (*Placebo*), 21 patients (66%) were between the age group of 16–25 years and 11 (34%) were between the age group of 26–35 years.

Among 65 patients, 29 were married and 36 were unmarried. Out of the 29 married, 11 had infertility issues (five patients in the interventional group and six in the control group). The most common clinical manifestations among the patients (both groups) were menstrual problems, which was seen in all 65 patients (Amenorrhoea - 9; Irregular menses - 56: 100%), followed by obesity in 21 patients (32%) [Table 1].

Menstrual status before intervention

In Group I, the average interval between two periods of menstrual cycle before the intervention was 138 days and in Group II, it was 65 days.

Menstrual status after intervention

In Group I, the menses were restored in an average interval of 31 days and in Group II, the menses were restored in an average interval of 37 days, between two periods of menstrual cycle after their respective intervention.

Menstrual status before and after intervention

Twelve out of 25 patients (i.e., 48%) got their menses in Group I (*Ferr. met*. 30C) and 6 out of 21 patients (i.e. 28.57%) got their menses in the Group II (Control Group), with one case reporting interval between two cycles in the treatment group reducing from 376 to 26 days. While in the control group, this difference was observed to be the most in a case where it reduced from 122 to 37 days.

Among the five women under the interventional group, menses appeared in one patient, and did not appear in another. Three patients dropped out (two women discontinued from the study due to non-compliance to treatment and one lost to follow-up). Among the six women under the control group, menses appeared in two patients, and did not appear in one patient. Three patients were dropped out (three women discontinued from the study due to non-compliance to treatment) [Table 2].

Out of total 46, 25 patients in Group I and 21 in Group II were thus considered for statistical analysis. The normality of the PCOSQ total score before and after the study was confirmed using Shapiro - Wilks test.

The improvement in menstrual cycle before and after intervention for patients in both groups, when tested for significance, showed a significant difference after the intervention (higher in Group I than Group II), thus confirming the efficacy of intervention in the experimental group: $p < 0.05$ [Table 3].

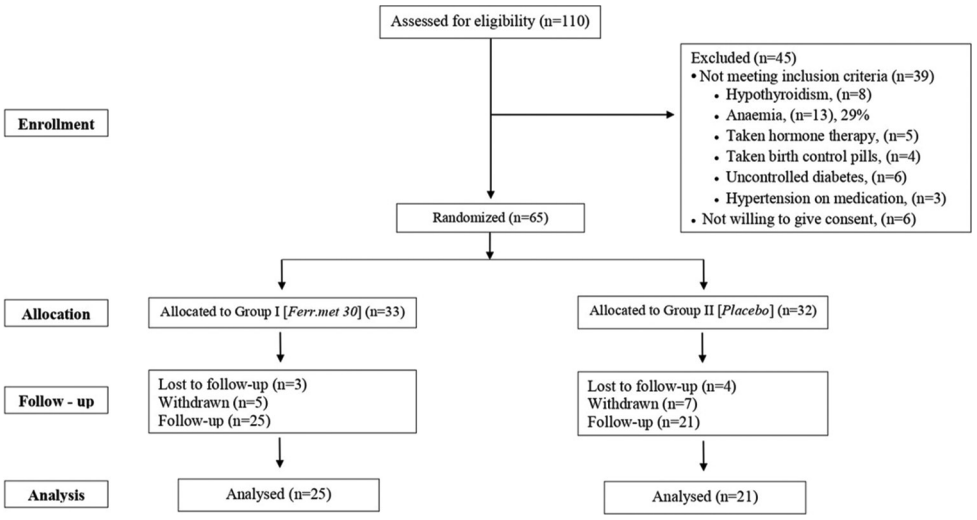

Figure 1: Study flow

Within-group comparison using the paired t-test showed a statistically significant improvement in the PCOSQ score from baseline to end in Group I (*Ferr. met*. 30C) [t = 2.93, $p = 0.007$, E.S. = 0.59] [Table 4]. There was no significant difference from baseline to end in Group II (Control Group).

The data were also compared for the menstrual restoration period in both the groups. About 48% participants in group I and 29% in group II had their menses restored after homoeopathic intervention and the difference between the groups was found to be 1.81 ($p < 0.05$).

Table 1: Clinical manifestations of PCOS in experimental and control groups

S. No.	Symptoms	n (%)	
		Experimental Group	Control Group
01	Amenorrhoea	4 (12)	5 (16)
02	Irregular menses	29 (88)	27 (84)
03	Obesity	8 (24)	13 (41)
04	Hirsutism	8 (24)	8 (25)
05	Dysmennorrhoea	5 (15)	4 (13)
06	Infertility	5 (15)	6 (19)
07	Acne in Face	2 (6)	4 (13)
08	Hyperpigmentation	3 (9)	3 (9)
09	Nausea and vomiting	2 (6)	2 (6)
10	Giddiness	2 (6)	1 (3)
11	Tiredness	1 (3)	1 (3)

The odds ratio of restoration of menses in the intervention group was 2.31 with a 95% CI (0.675, 7.89). The Chi-square test showed that there was no significant association between menstrual status and the intervention applied and Chi-square test for association was applied. $p < 0.05$ was considered as statistically significant.

The mean comparison, in the domains of PCOSQ scores on emotional status, infertility, and menstrual problem showed a significant improvement in the experimental group, in comparison to the in the control group [Table 5].

The paired samples statistics, in the domains of PCOSQ scores on emotional status, infertility and menstrual problem showed a significant improvement in the experimental group, in comparison to the control group [Table 6].

The paired sample test also showed a significant improvement in the domains of PCOSQ scores on emotional status, infertility, and menstrual problems in experimental group, when compared to the control group in these domains [Table 7].

Discussion

PCOS includes a range of complaints, especially menstrual irregularities, in most women. This prospective, randomised, placebo-controlled, single-blind trial suggests the efficacy of

Table 2: Menstruation status after the intervention

Group distribution	Menses appeared (1) and Menses did not appear (0) Cross tabulation		Total no. of patients taken up for the study	Withdrawn/dropout patients	Total no. of patients enrolled
	Menses appeared (1) and Menses did not appear (0)				
	Menses did not appear	Menses appeared			
Group					
I					
No. of patients	13	12	25	8	33
%	52	48	75.75	24.24	50.77
II					
No. of patients	15	6	21	11	32
%	71.43	28.57	65.63	34.38	49.23
Total					
No. of patients	28	18	46	19	65
%	60.87	39.13	70.77	29.23	-

Table 3: Between-group comparison of PCOSQ score

PCOSQ Score	Group	N	Mean±SD	Mean difference±SE	95% C.I for mean diff.	Test statistic (Students' t)	*p*-value	Effect size (Cohen's d)
Before	I	25	120±16.2	7.97±4.82	(−1.75, 17.7)	1.65	0.105	-
	II	21	112±16.4					
After	I	25	131±23.8	15.13±6.50	(2.03, 28.2)	2.33	0.025	0.69
	II	21	115±19.6					

PCOSQ: Polycystic ovarian syndrome questionnaire

Table 4: Within-group comparison of PCOSQ score

Group Distribution	Mean±SD		Mean difference±SE	95% CI for mean different	Test statistic (Students' t)	*p*-value	Effect size (Cohen's d)
	Before	After					
Group I	119.6±16.2	130.6±23.8	10.9±3.73	(3.26, 18.6)	2.93	0.007	0.59
Group II	111.67±16.4	115.43±19.6	3.76±3.59	(−3.73, 11.3)	1.05	0.308	-

Values are expressed as mean±SD. A paired t-test was conducted. $p<0.05$ was considered as statistically significant.

Table 5: Mean comparison

PCOSQ Domains	Mean (SD) of Group I		Mean (SD) of Group II	
	Before	After	Before	After
Emotion	26.00 (2.872)	30.64 (7.170)	26.71 (2.813)	27.67 (5.927)
Body Hair	29.36 (9.451)	29.00 (9.412)	28.10 (11.322)	28.95 (9.816)
Weight	26.64 (10.111)	26.52 (10.017)	20.19 (10.666)	19.81 (10.727)
Infertility	22.92 (5.299)	23.52 (4.806)	20.95 (6.975)	20.90 (6.752)
Menstrual problem	13.36 (2.737)	16.76 (5.718)	14.43 (2.561)	15.19 (5.240)

Table 6: Paired samples statistics

Group	Mean	N	Standard deviation	Standard error mean	*P*-value
I					
Emotions					
Before	26.00	25	2.872	0.574	**0.004***
After	30.64	25	7.170	1.434	
Body Hair					
Before	29.36	25	9.451	1.890	0.481
After	29.00	25	9.412	1.882	
Weight					
Before	26.64	25	10.111	2.022	0.784
After	26.52	25	10.017	2.003	
Infertility					
Before	22.92	25	5.299	1.060	**0.036***
After	23.52	25	4.806	0.961	
Menstrual problem					
Before	13.36	25	2.737	0.547	**0.007***
After	16.76	25	5.718	1.144	
II					
Emotions					
Before	26.71	21	2.813	0.614	0.487
After	27.67	21	5.927	1.293	
Body hair					
Before	28.10	21	11.322	2.471	0.280
After	28.95	21	9.816	2.142	
Weight					
Before	20.19	21	10.666	2.327	0.225
After	19.81	21	10.727	2.341	
Infertility					
Before	20.95	21	6.975	1.522	0.815
After	20.90	21	6.752	1.473	
Menstrual problem					
Before	14.43	21	2.561	0.559	0.497
After	15.19	21	5.240	1.144	

* Significant

Table 7: Paired samples test

Group	PCOSQ Domains	Intervention Differences	Paired differences					t	df	Sig. (2-tailed)
			Mean	Standard deviation	Standard error mean	95% Confidence interval of the difference				
						Lower	Upper			
I										
	Emotions	Before - After	−4.640	7.325	1.465	−7.664	−1.616	−3.167	24	**0.004***
	Body Hair	Before - After	0.360	2.515	0.503	−0.678	1.398	0.716	24	0.481
	Weight	Before - After	0.120	2.166	0.433	−0.774	1.014	0.277	24	0.784
	Infertility	Before - After	−0.600	1.354	0.271	−1.159	−0.041	−2.216	24	**0.036***
	Menstrual problem	Before - After	−3.400	5.788	1.158	−5.789	−1.011	−2.937	24	**0.007***
II										
	Emotions	Before - After	−0.952	6.168	1.346	−3.760	1.855	−0.708	20	0.487
	Body Hair	Before - After	−0.857	3.540	0.772	−2.468	0.754	−1.110	20	0.280
	Weight	Before - After	0.381	1.396	0.305	−0.254	1.016	1.251	20	0.225
	Infertility	Before - After	0.048	0.921	0.201	−0.371	0.467	0.237	20	0.815
	Menstrual problem	Before - After	−0.762	5.049	1.102	−3.060	1.536	−0.692	20	0.497

*Denotes there was significance $p<0.05$

Ferr. met. 30 C in regularising the menstrual cycle in patients suffering from PCOS along with an improvement in the quality of life observed in participants of both groups after intervention.

The participants enrolled in this study were in the age group of 16–35 years. This was consistent with the age groups seen in another randomised, placebo-controlled study of Homoeopathy in this condition, where the age group was 18–36 years,[14] and whereas in the study conducted by Shoaei *et al*., the participants enrolled were in the age group of 15–40 years.[15]

In this study, the mean interval between two periods of menstruation in the experimental group was markedly lesser by 31 days, when compared to the control group which was 37 days after intervention. In another similar study[16] to see the effect of homoeopathic medicines in PCOS, the average interval between two periods of menstruation was 40 days after intervention with the polychrest homoeopathic medicines (*Natrum mur, Pulsatilla, Lycopodium,Calcarea carb, Phosphorus, Borax, Graphities, Sepia and Kali phos*). This shows *Ferr. met*. 30C is effective in reducing the long and irregular menstrual cycles among women.

Comparing the baseline scores of the individual groups before and after treatment through PCOSQ, the experimental group showed significant improvement than control group in the domains of emotional status, infertility and especially menstrual problems, indicating the efficacy of the homoeopathic medicine *Ferr. met*. 30C. This observation was also found to be consistent with the studies conducted by Lamba *et al*[17] and Malvekar *et al*[16] We also observed that both groups showed no influence on the body hair and weight domain score of PCOSQ, similar to the observations in the studies conducted by Guyatt *et al*,[18] Bazarganipour *et al*,[19] Khomami *et al*[20] and Gollapudi *et al*.[21]

The study findings may be generalised, as the primary outcomes are significant for the sample size and study participants; yet, its broader applicability needs to be confirmed after various large scale studies.

The limitations noted in the study were small and convenient sample size of the study, thus challenging the applicability of the findings on a larger population. The study is a single blind trial and the results, thus, need external validation through double blind studies to ensure absence of bias. Loss-to-follow-up cases have been higher, which challenged the study continuation and compromised the primary outcome results in a smaller way. Thus, large scale double-blind studies are needed to confirm the applicability of our study results.

Conclusion

In this study, *Ferr. met*. 30C was found to be an effective intervention in restoring the menstrual cycle in patients with PCOS compared with placebo. The medicine also, had a potentially positive effect on the quality of life of the patients. More RCTs, especially double blind RCTs, with a larger sample size and with various homoeopathic medicines and potencies, are warranted.

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Efficacité de *Ferrum metallicum* 30C dans la restauration du cycle menstruel chez les patientes atteintes du syndrome des ovaires polykystiques - Essai randomisé, contrôlé par placebo, en simple aveugle

Contexte: Le syndrome des ovaires polykystiques (SOPK) est le trouble endocrinien le plus courant qui touche les femmes en âge de procréer, avec comme symptôme clinique prédominant une menstruation irrégulière. **Objectif:** Cet essai a évalué l'efficacité de *Ferr. met.* 30C dans la restauration du cycle menstruel chez les patientes atteintes du SOPK. **Méthodes:** Un essai randomisé, contrôlé par placebo, en simple aveugle a été mené dans les services ambulatoires du Sri Sai Ram Homoeopathy Medical College and Research Centre, à Chennai. Les patientes ont été réparties au hasard dans les groupes expérimental (Groupe I - Ferr. met. 30C) et témoin (Groupe II - Placebo). La qualité de vie des patientes des deux groupes a été évaluée au moyen d'une échelle de questionnaire sur le SOPK au départ et au 6e mois. **Résultats:** Soixante-cinq patientes ont été recrutées et assignées aléatoirement au groupe I (n = 33) et au groupe II (n = 32). Le cycle menstruel a été régularisé chez 48 % des patientes du groupe I et 29 % du groupe II. Les données ont également été comparées pour voir la période de restauration menstruelle dans les deux groupes. Environ 48 % des participantes du groupe I et 29 % du groupe II ont vu leurs règles restaurées après une intervention homéopathique et la différence entre les groupes s'est avérée être de 1,81 ($p < 0,05$). L'amélioration du cycle menstruel avant et après l'intervention pour les patientes des deux groupes a montré une différence significative après l'intervention (plus élevée dans le groupe I que dans le groupe II), confirmant l'efficacité de l'intervention dans le groupe expérimental : $p < 0,05$. **Conclusion:** Cet essai suggère que *Ferr. met.* 30C pourrait être efficace pour restaurer le cycle menstruel chez les patientes atteintes du SOPK. Des essais rigoureux et des réplications indépendantes sont nécessaires.

Wirksamkeit von *Ferrum metallicum* 30C bei der Wiederherstellung des Menstruationszyklus bei Patientinnen mit polyzystischem Ovarialsyndrom - eine randomisierte, placebokontrollierte, einfach verblindete Studie

Hintergrund: Das polyzystische Ovarialsyndrom (PCOS) ist die häufigste endokrine Störung bei Frauen im gebärfähigen Alter, wobei das vorherrschende klinische Symptom eine unregelmäßige Menstruation ist. **Ziel:** Diese Studie untersuchte die Wirksamkeit von *Ferr. met.* 30C bei der Wiederherstellung des Menstruationszyklus bei Patientinnen mit PCOS. **Methoden:** Eine randomisierte, placebokontrollierte, einfach verblindete Studie wurde in den Ambulanzen des Sri Sai Ram Homoeopathy Medical College and Research Centre, Chennai, durchgeführt. Die Patientinnen wurden nach dem Zufallsprinzip in die Versuchsgruppe (Gruppe I - Ferr. met. 30C) und die Kontrollgruppe (Gruppe II - Placebo) eingeteilt. Die Lebensqualität der Patientinnen in beiden Gruppen wurde zu Studienbeginn und nach sechs Monaten mithilfe des PCOS-Fragebogens beurteilt**. Ergebnisse:** 65 Patientinnen wurden aufgenommen und zufällig der Gruppe I (n = 33) und der Gruppe II (n = 32) zugeteilt. Der Menstruationszyklus regulierte sich bei 48 % der Patientinnen in Gruppe I und 29 % in Gruppe II. Die Daten wurden auch verglichen, um die Periode zur Wiederherstellung der Menstruation in beiden Gruppen zu ermitteln. Bei etwa 48 % der Teilnehmerinnen in Gruppe I und 29 % in Gruppe II setzte die Menstruation nach einer homöopathischen Intervention wieder ein, und der Unterschied zwischen den Gruppen betrug 1,81 ($p < 0,05$). Die Verbesserung des Menstruationszyklus vor und nach der Intervention zeigte sich bei Patientinnen in beiden Gruppen signifikant (höher in Gruppe I als in Gruppe II), was die Wirksamkeit der Intervention in der Versuchsgruppe bestätigt: $p < 0,05$. **Fazit:** Diese Studie legt nahe, dass *Ferr. met.* 30C könnte bei der Wiederherstellung des Menstruationszyklus bei PCOS-Patientinnen wirksam sein. Strenge Studien und unabhängige Replikationen sind erforderlich.

पॉलीसिस्टिक ओवेरियन सिंड्रोम रोगियों में मासिक धर्म चक्र को बहाल करने में *फेरम मेटालिकम 30C* की प्रभावकारिता - एक रेंडमाइज्ड, प्लेसबो-नियंत्रित, सिंगल-ब्लाइंड परीक्षण

पृष्ठभूमि: पॉलीसिस्टिक ओवेरियन सिंड्रोम (पीसीओएस) प्रजनन आयु की महिलाओं को प्रभावित करने वाला सबसे आम अंतःस्रावी विकार है, जिसमें अनियमित मासिक धर्म एक प्रचलित नैदानिक लक्षण है। **उद्देश्य:** इस परीक्षण ने पीसीओएस रोगियों में मासिक धर्म चक्र को बहाल करने में *फेरम मेट 30C* की प्रभावकारिता का आकंलन किया। **तरीके:** श्री साई राम होम्योपैथी मेडिकल कॉलेज और अनुसंधान केंद्र, चेन्नई के बाह्य रोगी विभागों में एक रेंडमाइज्ड, प्लेसबो-नियंत्रित, सिंगल-ब्लाइंड परीक्षण किया गया। रोगियों को रेंडमाइज्ड रूप से प्रायोगिक (समूह I - *फेरम मेट 30C*) और नियंत्रण (समूह II - प्लेसबो) समूहों में आवंटित किया गया। दोनों समूहों में रोगियों के जीवन की गुणवत्ता का आकंलन बेसलाइन और 6 महीने में पीसीओएस प्रश्नावली पैमाने के माध्यम से किया गया। परिणाम: पैंसठ रोगियों को नामांकित किया गया और रेंडमाइज्ड रूप से समूह I (n = 33) और समूह II (n = 32) में आवंटित किया। ग्रुप I के 48% रोगियों और समूह II के 29% रोगियों में मासिक धर्म चक्र नियमित हो गया। दोनों समूहों में मासिक धर्म की बहाली की अवधि देखने के लिए आंकड़ों की तुलना भी की गई। होम्योपैथिक हस्तक्षेप के बाद समूह I के लगभग 48% प्रतिभागियों और समूह II के 29% प्रतिभागियों के मासिक धर्म बहाल हो गए और समूहों के बीच अंतर 1.81 ($p < 0.05$) पाया गया। हस्तक्षेप के बाद, दोनों समूहों में एक महत्वपूर्ण अंतर पाया गया (समूह II की तुलना में समूह I में अधिक)),यह प्रयोगात्मक समूह में हस्तक्षेप की प्रभावकारिता की पुष्टि करता है ($p < 0.05$) । **निष्कर्ष:** यह परीक्षण बताता है कि *फेरम मेट 30 C* पीसीओएस रोगियों में मासिक धर्म चक्र को बहाल करने में प्रभावी हो सकती है

Eficacia de *Ferrum metallicum* 30C para restablecer el ciclo menstrual en pacientes con síndrome de ovario poliquístico: un ensayo aleatorizado, controlado con placebo y a simple ciego

Antecedentes: el síndrome de ovario poliquístico (SOP) es el trastorno endocrino más común que afecta a las mujeres en edad reproductiva, y el síntoma clínico predominante es la menstruación irregular. **Objetivo:** este ensayo evaluó la eficacia de *Ferr. met.* 30C para restablecer el ciclo menstrual entre pacientes con SOP. Métodos: se realizó un ensayo aleatorizado, controlado con placebo y a simple ciego en los departamentos ambulatorios de Sri Sai Ram Homoeopathy Medical College and Research Centre, Chennai. Las pacientes fueron asignadas aleatoriamente a los grupos experimental (Grupo I: *Ferr. met.* 30C) y de control (Grupo II: Placebo). La calidad de vida de las pacientes de ambos grupos se evaluó a través de la escala del Cuestionario de SOP al inicio y al sexto mes. **Resultados:** Se reclutaron sesenta y cinco pacientes y se asignaron aleatoriamente al Grupo I (n = 33) y al Grupo II (n = 32). El ciclo menstrual se regularizó en el 48 % de las pacientes del Grupo I y en el 29 % del Grupo II. También se compararon los datos para ver el período de restauración menstrual en ambos grupos. Alrededor del 48 % de las participantes del grupo I y del 29 % del grupo II recuperaron su menstruación después de la intervención homeopática y se encontró que la diferencia entre los grupos era de 1,81 ($p < 0,05$). La mejoría en el ciclo menstrual antes y después de la intervención para las pacientes de ambos grupos mostró una diferencia significativa después de la intervención (mayor en el Grupo I que en el Grupo II), lo que confirma la eficacia de la intervención en el grupo experimental: $p < 0,05$**. Conclusión:** Este ensayo sugiere que *Ferr. met.* 30C podría ser eficaz para restaurar el ciclo menstrual en pacientes con SOP. Se justifican ensayos rigurosos y réplicas independientes.

金屬鐵 30C 在恢復多囊性卵巢症候群患者月經週期中的功效 - 一項隨機、安慰劑對照、單盲試驗

【摘要】：背景:多囊性卵巢症候群(PCOS)是影響育齡婦女最常見的內分泌疾病,其普遍的臨床症狀是月經不規則。目的：本試驗評估了 Ferr 的療效。遇見了。 30C 恢復 PCOS 患者的月經週期。方法：在欽奈 Sri Sai Ram 順勢療法醫學院和研究中心的門診部進行了一項隨機、安慰劑對照、單盲試驗。患者被隨機分配到實驗組（第一組 - *Ferr.met*.30C）和對照組（第二組 - 安慰劑）。以 PCOS 問卷量表評估基線和第 6 個月時兩組患者的生活品質。結果：65 位患者入組並隨機分爲第一組 (n = 33) 和第二組 (n = 32)。 I 組中 48% 的患者和 II 組中 29% 的患者月經週期變得規律。也比較數據以了解兩組的月經恢復期。在順勢療法介入後，第一組中約 48% 的參與者和第二組中約 29% 的參與者恢復了月經，組間差異爲 1.81（$p < 0.05$）。兩組患者介入前後的月經週期改善在介入後均有顯著差異（I組高於II組），證實了實驗組介入的有效性：$p < 0.05$。結論：這項試驗顯示 *Ferr。遇見了。* 30℃可有效恢復PCOS患者的月經週期。嚴格的試驗和獨立的複製是必要的。