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Effect of Loboob, a Traditional Persian Multi-Herbal Formulation, on Semen Parameters and Pregnancy Outcomes: A Double-Blind Randomized Placebo-Controlled Clinical Trial

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Abstract

Despite advances in assisted reproductive technologies, overall success rates remain modest, prompting many couples to explore complementary and alternative therapies. Loboob, a traditional Persian multi-herbal formulation, has historically been used to enhance male reproductive health, yet robust human data are lacking. To evaluate the effects of Loboob on semen parameters and pregnancy outcomes in infertile men. In this double-blind, randomized, placebo-controlled pilot trial, 44 infertile men were equally assigned to Loboob or placebo groups. The intervention group received 5 cc of Loboob twice daily for three months; controls received placebo. Both groups received standardized lifestyle and dietary recommendations based on Traditional Persian Medicine. Semen analysis was performed at baseline and three months. Pregnancy was confirmed by maternal β-hCG within six months and monitored to delivery. Independent t-test and Chi-square were used, with significance at $p < 0.05$. Loboob significantly improved semen volume ($p = 0.039$), sperm count ($p = 0.030$), and motility ($p = 0.017$) compared with placebo, while morphology showed no significant change ($p = 0.574$). During follow-up, 10 pregnancies occurred in the Loboob group (47.6%) and 7 in the placebo group (31.8%) ($p = 0.45$). All pregnancies progressed to term and resulted in healthy live births, with no miscarriages. Loboob improved semen volume, count, and motility, though pregnancy outcomes did not differ significantly between groups. Larger, multi-center trials with extended follow-up are needed to validate these findings and clarify the role of Loboob as an adjunctive therapy for male infertility.

Keywords: Loboob, Traditional Persian Medicine, male infertility, sperm parameters, randomized controlled trial

1. Introduction

Infertility is recognized as a major global health concern, affecting approximately 15% of couples worldwide and exerting profound emotional, psychological, and social burdens on affected individuals [1-4]. Male factor infertility accounts for nearly half of all infertility cases, with etiologies that include congenital or acquired testicular abnormalities, endocrine dysfunctions, exposure to gonadotoxic agents, oxidative stress, and idiopathic causes [5-7]. Despite advances in assisted reproductive technologies (ART), limitations in success rates, high costs, and the associated physical and emotional challenges have encouraged many couples to explore complementary and alternative medicine (CAM) as potential adjunctive therapies [8].

Herbal medicine is among the most widely used forms of CAM, with reports suggesting that nearly 70–80% of people worldwide have used herbal remedies at some point in their lives [9]. Patients often perceive herbal treatments as safer, less invasive, and more natural alternatives to pharmacological therapies. Within the context of male infertility, a growing body of evidence has suggested that antioxidants and phytochemicals derived from medicinal plants may enhance sperm quality by mitigating oxidative stress, improving mitochondrial function, and modulating hormonal balance [10-13]. Nevertheless, the available evidence from clinical trials remains limited and often controversial, with many studies restricted to experimental animal models [14-16].

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Loboob, also known as *Majoon-e Laboob* in Traditional Persian Medicine (TPM), is a multi-herbal formulation historically prescribed to improve male fertility and sexual vigor.

This compound is composed of various medicinal plants and natural ingredients, many of which are rich in antioxidants, flavonoids, and essential nutrients that may positively influence spermatogenesis, libido, and

This compound is composed of various medicinal plants and natural ingredients, many of which are rich in antioxidants, flavonoids, and essential nutrients that may positively influence spermatogenesis, libido, and testicular function [17]. According to TPM literature, Loboob is considered a "sperm booster" and a corrector of cold temperament—a traditional concept believed to contribute to male infertility. Experimental studies in animal models have suggested beneficial effects of Loboob on semen parameters, particularly at higher doses, but rigorous clinical evidence in humans remains scarce [18, 19].

Given the widespread use of herbal remedies among infertile men and the limited availability of high-quality clinical data, there is a pressing need to evaluate the therapeutic potential of Loboob in controlled clinical settings. To address this gap, we designed a double-blind, randomized, placebo-controlled pilot trial to investigate the effect of Loboob on semen parameters and pregnancy outcomes in infertile men. This study aims to provide preliminary clinical evidence on the efficacy and safety of this traditional multi-herbal formulation, thereby contributing to both the scientific understanding of herbal interventions in male infertility and the integration of traditional medicine into modern therapeutic approaches.

Methods

2.1. Study Design and Participants

This double-blind, randomized, placebo-controlled clinical trial was conducted as a prospective pilot study on 44 infertile men recruited from the traditional medicine clinic affiliated with Shiraz University of Medical Sciences between December 2024 and January 2025 (clinical trial number: IRCT201508036541NB). The flowchart of the study is presented in Fig. 1.

Eligible participants were infertile men with a body mass index (BMI) below 30 kg/m², who had not received hormone or complementary therapies in the preceding six months.

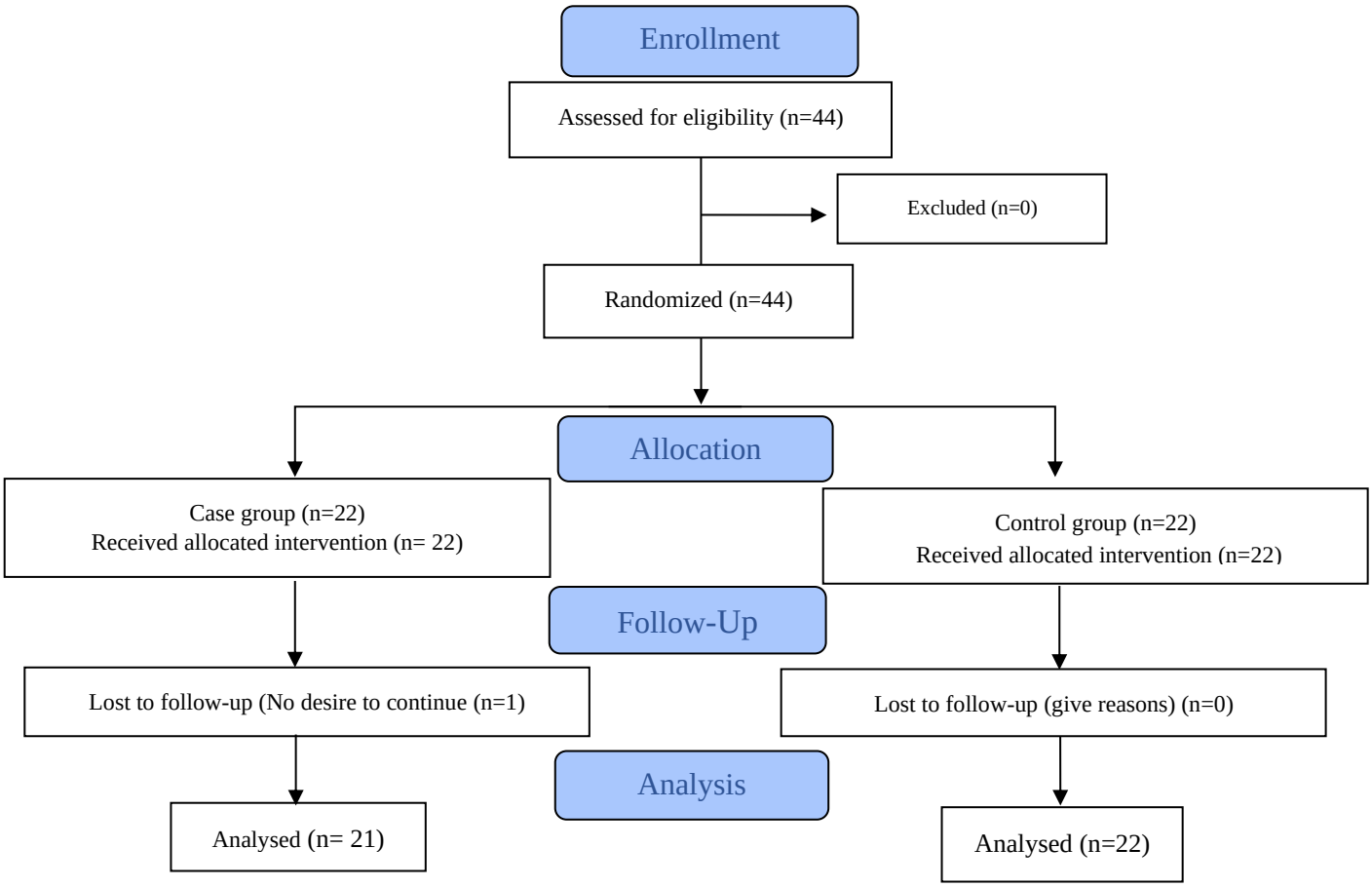

Figure 1: Flow diagram of study population

Exclusion criteria included chronic systemic diseases (such as diabetes mellitus, hypertension, thyroid, renal, hepatic disease, or cancer), allergies to milk or Loboob components, and unwillingness to continue participation. One patient in the Loboob group discontinued treatment, leaving 43 subjects for final analysis. Written informed consent was obtained from all participants, and the study was approved by the Ethics Committee of Shiraz University of Medical Sciences (IR.SUMS.REC.1394.56).

2.2. Randomization and Intervention

Participants were randomized equally into two groups using block randomization with sealed opaque envelopes. The intervention group received 5 cc of Loboob twice daily, followed by a glass of warm milk, for a three-month period. The placebo group received a preparation of identical appearance and consistency. The Loboob formulation was prepared in accordance with a modified method described in previous experimental studies, consisting of a combination of herbal ingredients and honey (Table 1).

Table 1: Ingredients and Temperaments of the ingredients

	Ingredient	Family	Used part[#]	Percentage	Temperament*	Voucher number
1	*Allium cepa* L.	Amaryllidaceae	S	0.8	H2 D2	PTMI 107
2	*Alpinia officinarum* Hance	Zingiberaceae	R	0.8	H2 D2	PTMI 108
3	*Boswellia carterii* Birdw.	Burseraceae	O	0.8	H2 D2	PTMI 109
4	*Brassica rapa* L.	Brassicaceae	S	1.6	H3 W1	PTMI 118
5	*Cinnamomum zeylanicum* Blume	Lauraceae	B	0.8	H2 D2	PTMI 110
6	*Cocos nucifera* L.	Arecaceae	F	1.6	H2 D2	PTMI 101
7	*Corylus avellana* L.	Betulaceae	K	1.6	H1 D1	PTMI 102
8	*Juglans regia* L.	Juglandaceae	K	1.6	H2 D1	PTMI 103
9	*Lepidium perfoliatum* L.	Brassicaceae	S	1.6	H2 W1	PTMI 111
10	*Mentha piperita* L.	Lamiaceae	L	1.6	H2 D2	PTMI 112
11	*Piper cubeba* L.F.	Piperaceae	F	0.8	H2 D2	PTMI 113
12	*Piper nigrum* L.	Piperaceae	F	0.8	H3 D3	PTMI 114
13	*Pistacia vera* L.	Anacardiaceae	K	1.6	H2 D2	PTMI 104
14	*Prunus dulcis* Mill.	Rosaceae	K	1.6	H1 W1	PTMI 105
15	*Sesamun indicum* L.	Pedaliaceae	S	1.6	H1 W1	PTMI 106
16	Sugar	-	-	1.6	H2 D1	-
17	*Syzygium aromaticum* (L.) Merr.& L.M.Perry	Myrtaceae	Bu	0.8	H3 D3	PTMI 115
18	*Withania somnifera* (L.) Dunal	Solanaceae	R	0.8	H2 D2	PTMI 116
19	*Zingiber officinale* Roscoe	Zingiberaceae	Rh	0.8	H3 D2	PTMI 117
20	Honey	-	-	≈ 76	H2 D1	-

S: Seed, R: Root, O: Oil or Ovary (less common), B: Bark, F: Fruit, K: Kernel or sometimes Rhizome, L: Leaf, Bu: Bulb, Rh: Rhizome.
H = Hot, C = Cold, D = Dry, W = Wet. The number (1–4) indicates the degree of that quality.

2.3. Lifestyle and Dietary Counseling

In addition to the allocated intervention, all participants received standardized dietary and lifestyle recommendations based on Traditional Persian Medicine principles. Patients were advised to avoid overeating and binge eating, consume food combinations containing chickpeas, fish or shrimp, and carrots once or twice weekly, and eat fruits such as grapes, pears, or apples daily. Furthermore, they were encouraged to adopt regular sleep hygiene practices by going to bed approximately one hour before midnight and to engage in light physical activity, specifically walking for about 15 minutes daily. These recommendations were provided by the same traditional physician to ensure consistency.

2.4. Outcome Measures

Baseline demographic data, medical history, and physical examination findings were collected at enrollment. Semen samples were obtained at baseline and after three months of treatment following 2–5 days of abstinence, and were analyzed according to World Health Organization (WHO, 1999) guidelines. Parameters measured included semen volume, sperm count, motility, and morphology. Pregnancy outcomes were assessed through serial β-hCG testing over a six-month follow-up period, and the clinical course of pregnancies in women

who conceived was monitored until delivery. Side effects or adverse events were recorded during monthly visits.

2.5. Statistical Analysis

Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables as frequency and percentage. Independent t-tests and Mann–Whitney U tests were applied for continuous variables, while Chi-square tests were used for categorical data. A p-value < 0.05 was considered statistically significant. Data analyses were conducted using SPSS version 21.

3. Results

A total of 44 patients were recruited and randomized equally into the intervention (Loboob) and placebo groups. One participant in the Loboob group did not continue Loboob consumption and withdrew from the study protocol, leaving 43 subjects for the final analysis (Figure I). Baseline demographic and clinical characteristics, including age, body mass index (BMI), duration and type of infertility, and presence of varicocele, were comparable between the two groups, with no statistically significant differences (Table 2).

Table 2: Demographic data of case and control groups

	Case n=21	Control n=22	P-value
age(years)	33.62 ± 6.44	35.36 ± 5.57	0.345
BMI	25.07 ± 3.41	24.01 ± 4.24	0.410
Duration of Infertility(years)	4.5 ± 3.22	5.13 ± 4.23	0.591
Varicocele Presence	13(61.90%)	13 (59.09%)	0.851
Primary Infertility	14 (66.67%)	16 (72.73%)	0.660
Secondary infertility	7 (33.33%)	6 (27.27 %)	0.660

3.1. Semen Parameters

Analysis of semen characteristics revealed significant differences between the intervention and control groups over the course of treatment. Figure II summarizes the comparative effects of Loboob (Group 1) and placebo (Group 2) on semen volume, sperm count, motility, and morphology at baseline and after three months. As shown, improvements were particularly notable in semen volume, sperm count, and motility, whereas morphology did not exhibit significant changes between the groups. Detailed results for each parameter are presented below.

3.2. Semen Volume

At baseline, no significant difference was observed between the two groups ($p = 0.873$). After the intervention, the Loboob group showed a significant increase in semen volume compared with the placebo group ($p = 0.039$) (Fig. 2A).

3.3. Sperm Count

Initial sperm counts were similar between groups ($p = 0.956$). Following the intervention, the Loboob group demonstrated a significant improvement compared with placebo ($p = 0.030$) (Fig. 2B).

3.4. Sperm Morphology

Normal morphology did not differ significantly between groups at baseline ($p = 0.958$) or after treatment ($p = 0.574$) (Fig. 2C).

3.5. Sperm Motility

Baseline motility values were comparable ($p = 0.959$). After three months, the Loboob group exhibited a significant improvement in motility compared with the placebo group ($p = 0.017$) (Fig. 2D).

3.6. Pregnancy Outcomes

During the three-month follow-up, 10 partners in the Loboob group (47.6%) and 7 partners in the placebo group (31.8%) achieved clinical pregnancy ($p = 0.45$). All pregnancies resulted in healthy live births, with no miscarriages reported. The mean birth weight was 2.75 ± 0.32 kg in the Loboob group and 2.89 ± 0.83 kg in the placebo group ($p = 0.679$).

4. Discussion

This randomized placebo-controlled pilot trial showed that Loboob significantly improved semen volume, sperm count, and motility after three months, with no effect on morphology. Pregnancy rates were similar between groups (10 in loboob vs. 7 in placebo group), and all resulted in healthy live births. While not statistically significant, these findings suggest Loboob may serve as a supportive therapy for male infertility.

The observed improvements in semen volume, count, and motility are consistent with the traditional use of Loboob as a fertility-enhancing formulation. The antioxidant and anti-inflammatory properties of several ingredients, including Cinnamomum zeylanicum, Sesamum indicum, Juglans regia, and Withania somnifera, may underlie these effects by reducing oxidative stress, preserving sperm DNA integrity, and enhancing mitochondrial function [20-22]. Improvements in motility in particular are of clinical importance, as motility is a key determinant of fertilization success [23-25]. The lack of significant improvement in morphology, however, suggests that the beneficial effects of Loboob may be more pronounced on sperm function rather than structural integrity, at least in the short term.

Our findings are in line with previous experimental and clinical studies suggesting positive effects of herbal formulations on sperm parameters. For instance, Withania somnifera and Sesamum indicum have been reported to enhance sperm quality and hormonal balance, while walnuts and almonds have been linked with improvements in sperm motility and viability [26-28]. A prior case series on Loboob in men with idiopathic infertility suggested improvements in sperm quality and conception rates, although the dosage and duration of treatment differed [29]. Notably, higher doses of Loboob in experimental rat models have demonstrated stronger beneficial effects, supporting the possibility of a dose-response relationship [18, 30].

Although pregnancy rates were numerically higher in the Loboob group, statistical significance was not achieved, likely due to the small sample size. Importantly,

participants were followed for only six months after treatment. Beyond this period, follow-up was continued exclusively for women who became pregnant in order to monitor pregnancy outcomes. It is plausible that the beneficial effects of Loboob on spermatogenesis and hormonal balance may require a longer duration to translate into higher conception rates. Spermatogenesis itself is a cyclical process spanning approximately three months, and repeated cycles influenced by improved testicular microenvironment and reduced oxidative stress may further enhance fertility outcomes. Thus, with extended follow-up of one year or longer, it is possible that additional pregnancies would be observed beyond those reported in this study. This consideration underscores the need for longer-term clinical trials to fully evaluate the impact of Loboob on reproductive success.

Several limitations should be noted. First, the sample size was relatively small, limiting statistical power. Second, only a single dose of Loboob was tested, and the possibility remains that higher or prolonged dosing might yield stronger effects. Third, semen parameters were only assessed up to three months, and pregnancy outcomes were followed for six months. A longer follow-up period may better capture the sustained and delayed effects of Loboob on fertility. Finally, unmeasured confounders such as diet adherence, partner-related factors, and lifestyle habits may have influenced the outcomes.

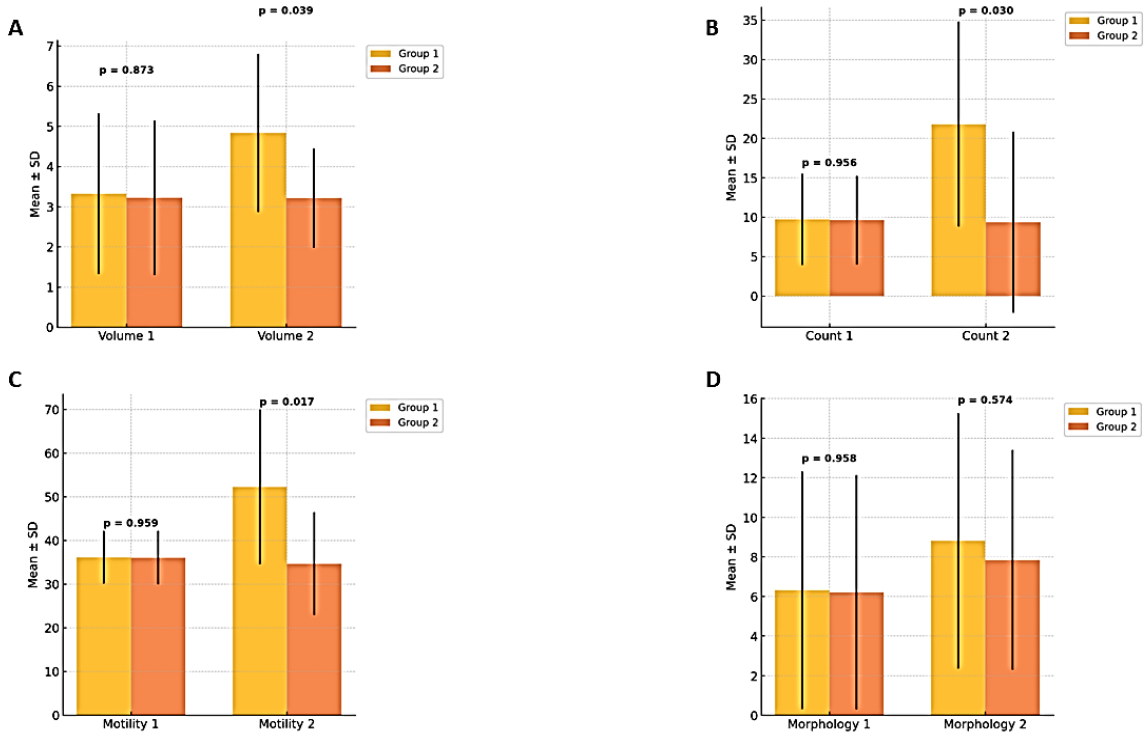

Figure 2: Effect of Loboob on semen parameters compared with placebo (control). (A) Semen volume, (B) sperm count, (C) sperm motility, and (D) normal sperm morphology was measured at baseline (1) and after three months of intervention (2). Data are presented as mean ± standard deviation (SD). Statistical comparisons between groups were performed using independent t-test. Group 1 = Loboob intervention; Group 2 = control (placebo).

5. Conclusion

In summary, this randomized pilot trial demonstrated that Loboob significantly improved semen volume, sperm count, and motility in infertile men, while morphology remained unchanged. Although pregnancy outcomes did not differ significantly between groups during the six-month follow-up, the potential for greater benefits with extended treatment or longer observation remains. It is possible that additional pregnancies would occur with one year or more of follow-up, highlighting the need for larger and longer-term clinical investigations.

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Data availability

The raw data can be obtained on request from the corresponding author.

Ethical approval

The Medical Ethics Committee of Shiraz University of Medical Sciences approved this study with the reference number IR.SUMS.REC.1394.56. All participants have signed the informed consent form.

Clinical trial number

IRCT201508036541NB.

Competing interests

The authors declare no competing interests.

Statement of using AI

The grammar of this text was edited using AI.

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