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A Randomized, Single-blind Comparative Clinical Trial on the Efficacy of Two Unani Formulations in Obese Patients

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ABSTRACT

Objective: Obesity is a growing global public health concern, significantly contributing to the onset of comorbid conditions such as diabetes, cardiovascular diseases, hypertension, cancer, musculoskeletal disorders, respiratory problems, and psychological issues. In Unani medicine, several formulations have been proposed for managing obesity, but they have not been scientifically investigated. Therefore, this study aims to evaluate the efficacy of two Unani formulations in treating obesity.

Materials and Methods: A randomized, single-blind, comparative clinical trial was conducted on 60 patients diagnosed with obesity. The participants were randomly divided into two groups: a test group (n=30) and a control group (n=30). The test formulation, Safoof Darchini, and the control formulation, Safoof Muhazzil, were administered as powders at a dose of 5g twice daily after meals, accompanied by warm water, for a duration of 90 days. Both groups were assessed fortnightly. The effect of the formulations was evaluated based on objective parameters such as weight, waist circumference, body mass index (BMI), and lipid profile, with assessments before and after the intervention. Statistical methods were used to analyze the outcomes.

Results: After 90 days of treatment, significant improvements were observed in weight, waist circumference, BMI, and lipid profile ($p<0.05$).

Conclusion: The results of this clinical trial indicate that Safoof Darchini is as effective as Safoof Muhazzil in managing obesity. While both formulations showed effectiveness in treating mild to moderate obesity, neither was effective in cases of morbid obesity. This study demonstrates that both formulations are effective and safe for managing obesity. However, larger studies with more robust designs are needed to generalize these findings.

Keywords Obesity, Unani Formulations, Unani Medicine, Safoof Darchini

INTRODUCTION

Obesity is a common health condition marked by the excessive buildup of body fat, resulting in a substantial increase in body weight.[1] It is a complex, multifactorial condition that arises from a disparity between energy consumption and expenditure.[2] In other words, when an individual takes in more calories than they expend through physical activity and metabolic functions, the surplus energy is stored as fat, leading to weight gain.[3] Obesity is a significant public health issue with wide-ranging effects on both individuals and society at large.[4]

Obesity is linked to numerous health risks and can play a role in the onset of several chronic conditions, such as type 2 diabetes, heart disease, specific cancers, and musculoskeletal issues.[5] Obesity can also adversely affect mental health, contributing to issues like depression and reduced self-esteem.[6] The causes of obesity are multifaceted, involving a combination of genetic, environmental, and behavioral factors.[7] Unhealthy eating habits, lack of physical activity, and genetic factors can all contribute to the development of obesity.[8]

Preventing and managing obesity typically involves a comprehensive approach, including changes in lifestyle, dietary

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habits, increased physical activity, and, in some cases, medical treatments.[9] Although the current medications for treating obesity are limited in number and effectiveness, examples include Sibutramine and Orlistat.[10]

Apart from modern medicine in Unani system of medicine *Simane Mufrit* (Obesity) is a phlegmatic disease in which temperament of body becomes abnormally cold and moist that results in excessive accumulation of fats (*Sheham wa Sameen*) leading to obesity.[11] Unani physicians such as Ibn Sina, Daud Antaki, Zakaria Razi, Ismail Jurjani, and Rabban Tabri provided detailed descriptions of the historical background, etiology, types, signs and symptoms, clinical diagnosis, and management of obesity.[12]

Given the above information, the study aimed to examine the effects of the test drug Darchini in comparison to Safoof Muhazzil for its anti-obesity properties.[13,14] This drug has been studied previously and reported to possess Musakhkhin (calorific), Muharrik (stimulant), Mufatteh-e-Sudad (deobstruent), hypoglycemic, and hypolipidemic effects.[15] It also has a hot and dry temperament, which helps increase the body's metabolic rate, burns excess fat, and contributes to the reduction of obesity.

On the other hand, the control drug, Safoof Muhazzil, has been recognized for its anti-obesity effects in Unani pharmacopeia (Qarabadeen).[15,16] This Unani formulation exhibits properties such as Muhazzil, Musakhkhin, Mudir (diuretic), and Mulattif (demulcent) due to its ingredients, including Zeera siyah (Carum carvi), Ajwain (Trachyspermum ammi), Marzanjosh (Origanum majorana), Badiyan (Foeniculum vulgare), LukMaghsool (Cocos lacca), Bura Armini (Sodium borate), and Suddab (Ruta graveolens), which are beneficial in reducing obesity.[17-19]

MATERIALS AND METHODS

This randomized, single-blind, comparative clinical trial was conducted to evaluate the efficacy of *Safoof Darchini* in comparison to *Safoof Muhazzil* for the treatment of obesity. The trial took place in the Department of Medicine at A.K.T.C. Hospital, Aligarh, from July 2017 to May 2019. Ethical clearance for the study was obtained from the Institutional Ethical Committee in 2017, with the ethical code 272/IEC/FUM/AMU/2017 assigned. A total of 150 individuals were screened for the study, of which 90 were excluded: 60 did not meet the inclusion criteria, 25 declined to provide consent, and 5 were excluded for other reasons. The remaining 60 participants were enrolled after obtaining written informed consent. The participants were then divided into two groups: the test group (Group A) and the control group (Group B), with 30 patients in each group (Table 1). The treatment protocol lasted for 90 days, with follow-up visits every two weeks. Patient selection and the efficacy of the test drug were evaluated based on medical history and objective parameters, including weight gain, waist circumference, BMI, and lipid profile. Patients in both groups were closely monitored and advised to follow a controlled diet and engage in regular exercise, such as brisk walking. The results of the test drug were recorded on a specially designed Case Report Form (CRF), and conclusions were drawn through appropriate statistical analysis.

Criteria for selection of subjects

Patients were selected and recruited from the OPD of A.K.T.C. Hospital, Aligarh. The inclusion criteria included diagnosed cases of obesity from both sexes, with a BMI greater than 25, waist circumference exceeding 102 cm in men and 88 cm in women. Eligible participants were those who could actively engage in the study, agreed to follow the instructions, and provided written consent. The age range for inclusion was 20 to 60 years, and patients with associated symptoms such as dyspnea, fatigue, weakness, palpitations, limited mobility, and joint pain were also considered. The exclusion criteria included patients under 20 years of age or over 60 years, those who did not provide written consent, pregnant or lactating women, individuals who failed to attend follow-up appointments, patients using estrogen-containing contraceptive pills, individuals with portal hypertension, and patients suffering from hypothyroidism, diabetes mellitus, chronic renal failure, nephrotic syndrome, HIV, cirrhosis of the liver, chronic alcoholism, primary gout, or

Table 1. Demographic Data of Patients in Test and Placebo group (n= 60)

Age of Group	N	Percentage	Mizaj	n	Percentage
20-30	24	40	Balghami	47	78.3
31-40	15	25	Damvi	13	21.6
41-50	13	21.6	Safrawi	0	0
51-60	8	13.3	Saudavi	0	0
Gender			**Religion**		
Male	35	58.3	Muslim	43	-
Female	25	41.7	Non-Muslim	17	-
S.E.S			**Marital Status**		
Upper (I)	6	10	Married	41	68.3
Upper Middle (II)	13	21.7	Unmarried	19	31.7
Lower Middle (III)	16	26.7	**Dietary Habits**		
Upper Lower (IV)	14	23.3	Vegetarian	17	28.3
Lower (V)	11	18.3	Mixed	43	71.7

bleeding disorders.

Investigations

Various investigations were conducted with the aim of establishing the safety of the test drug and diagnosing obesity caused by any metabolic disorders for exclusion from the study. The following tests were performed on all patients: TLC, DLC, RBC count, ESR, Hb%, RFT, LFT, lipid profile (including total cholesterol, triglycerides, and HDL), blood sugar (random and postprandial), and urine tests (routine and microscopic). These investigations were conducted both before the trial began and after its completion. Additionally, thyroid profile, RBS, and ECG were performed prior to the study to rule out other potential diseases.

Administration of drug

The test group received Safoof Darchini at a dosage of 5 g twice daily, while the control group was given Safoof Muhazzil at 5 g twice daily after meals with lukewarm water. Patients were advised to follow a dietary plan with a daily intake of fewer than 1300 calories and engage in moderate exercise, such as a brisk 20–30-minute walk in the morning or evening. No additional treatments were prescribed during the trial period.

Follow up assessment

The 90-day study was structured into seven follow-up visits; each conducted every two weeks. During each visit, patients were asked about any improvements in their symptoms, and examinations were performed to assess clinical findings.

Withdrawal criteria

If a subject is unwilling to continue, experiences adverse reactions, develops any acute systemic illness during the treatment, shows intolerance to the protocol, or fails to comply with the study requirements, they will be excluded.

Assessment of Safety

All adverse events reported by patients or observed by the investigator were documented at each visit. Adverse drug reactions were evaluated using the Naranjo ADR probability scale, along with assessments of onset and severity. A physical examination, including vital signs, was conducted at the start of the trial and during each follow-up visit. Additional laboratory safety parameters, such as haemogram (TLC, DLC, RBC, Hb%, ESR), LFT, and RFT, were also performed before and after the completion of the trial.

Assessment of Efficacy

The efficacy of the test and control groups was evaluated based on objective parameters, which included weight gain, waist circumference, BMI, and lipid profile. Upon completion of the trial, pre- and post-treatment values and scores were recorded and assessed. These results were compared, and statistical analysis was conducted to determine the effectiveness of the test and control drugs.

Outcome Measures

This includes achieving weight reduction to normal levels, bringing BMI within the normal range, reducing waist circumference to a healthy range, improving the lipid profile, and alleviating clinical symptoms associated with obesity.

Statistical Analysis

The paired and unpaired student's t-test was used for analyzing subjective value parameters, or other statistical tests were applied as necessary based on the data. Results were expressed as mean ± SD and considered statistically significant at $p<0.05$ (5% significance level).

RESULT

In this study, among the 60 patients diagnosed with Simane Mufrit (Obesity), 24 patients were in the 20-30 years age group, 15 patients were in the 31-40 years age group, 13 patients were in the 41-50 years age group, and 8 patients were in the 51-60 years age group. The highest prevalence of obesity was observed in the 20-30 years age group. The male patient population constituted 58.3%, which was slightly higher than the female patient population at 41.7%. The demographic data for both the test and control groups are presented in the table (Table 1).

The Effect of Test Drug on Objective Parameters

Effect on Serum Cholesterol

In the test group, the mean serum cholesterol level was 233.23 ± 64.08 mg/dl before treatment, which decreased to 194.1 ± 52.85 mg/dl at the end of the study. This resulted in a mean reduction of 39.23 ± 11.23 mg/dl, which was statistically significant ($P<0.001$). In the standard group, the mean serum cholesterol level was 204.03 ± 39.44 mg/dl before treatment, and at the conclusion of the study, it reduced to 190.06 ± 37.24 mg/dl, with a mean reduction of 13.97 ± 2.2 mg/dl, which was also statistically significant ($P<0.0035$) (Table 2).

Effect on Weight of the Body

In the test group, the mean body weight was 72.93 ± 9.32 kg before treatment, which decreased to 67.91 ± 9.57 kg at the end of the study. This resulted in a mean reduction of 5.02 ± 0.25 kg, which was statistically significant ($P<0.001$). In the standard group, the mean body weight was 72.26 ± 6.39 kg before treatment, and by the end of the study, it decreased to 68.77 ± 7.2 kg, showing a mean reduction of 3.49 ± 0.81 kg, which was also statistically significant ($P<0.001$) (Table 2).

Table 2. Various Changes of Objective Parameters in Tests and Placebo Group (n=60)

S. No.	Parameter	Group A			Group B		
		Before Treatment (Baseline)	After 90 Days	p- Value	Before Treatment (Baseline)	After 90 Days	p- Value
1	Weight of the Body	72.93±9.32	67.91±9.57	<0.0001	72.26 ± 6.39	68.77±7.2	<0.0001
2	Waist Circumference	96.5±6.81	95.43 ± 6.2	<0.0001	95.4 ± 5.53	93.68±5.5	<0.0001
3	BMI	28.9±2.26	26.88±2.57	<0.0001	28.58 ± 1.95	27.21±2.18	<0.0001
4	Serum Cholesterol	233.23±64.08	194.1±52.85	<0.0001	204.03±39.44	190.06±37.24	<0.0035
5	Serum Triglyceride	188.56±28.16	164.46±29.64	<0.0001	181.4 ± 55.91	161.9±52.73	<0.0001
6	HDL	28.43±5.88	41.1 ± 6.51	<0.0001	35.7 ± 6.68	44.16 ± 7.76	<0.0001

Effect on Waist Circumference

In the test group, the mean waist circumference was 96.5 ± 6.81 cm before treatment, which reduced to 95.43 ± 6.2 cm by the end of the study. This represented a mean reduction of 1.07 ± 0.61 cm, which was statistically significant (P<0.001). In the standard group, the mean waist circumference was 95.4 ± 5.53 cm before treatment, and decreased to 93.68 ± 5.5 cm at the conclusion of the study, showing a mean reduction of 1.72 ± 0.03 cm, which was also statistically significant (P<0.001) (Table 2).

Effect on BMI

In the test group, the mean BMI was 28.9 ± 2.26 kg/m² before treatment, which decreased to 26.88 ± 2.57 kg/m² by the end of the study. This resulted in a mean reduction of 2.02 ± 0.31 kg/m², which was statistically significant (P<0.001). In the standard group, the mean BMI was 28.58 ± 1.95 kg/m² before treatment, and reduced to 27.21 ± 2.18 kg/m² at the conclusion of the study, with a mean reduction of 1.37 ± 0.23 kg/m², also found to be significant (P<0.001) (Table 2).

Effect on Serum Triglyceride

In the test group, the mean serum triglyceride level was 188.56 ± 28.16 mg/dl before treatment, which decreased to 164.46 ± 29.64 mg/dl by the end of the study. This represents a mean reduction of 24.1 ± 1.48 mg/dl, which was statistically significant (P<0.001). In the standard group, the mean serum triglyceride level was 181.4 ± 55.91 mg/dl before treatment, and reduced to 161.9 ± 52.73 mg/dl at the end of the study, with a mean reduction of 19.5 ± 3.18 mg/dl, also found to be significant (P<0.001) (Table 2).

Effect on HDL

In the test group, the mean serum HDL level was 28.43 ± 5.88 mg/dl before treatment, which increased to 41.1 ± 6.51 mg/dl by the end of the study, showing a mean increase of 12.67 ± 0.63 mg/dl, which was statistically significant (P<0.001). In the standard group, the mean serum HDL level was 35.7 ± 6.68 mg/dl before treatment, and increased to 44.16 ± 7.76 mg/dl at the end of the study, with a mean increase of 8.46 ± 1.08 mg/dl, also found to be significant (P<0.001) (Table 2).

DISCUSSION

Obesity is a multifactorial condition that contributes significantly to the global burden of diseases, including metabolic disorders, cardiovascular diseases, and psychological issues.[20] Given the increasing prevalence of obesity, it is crucial to explore effective treatment options that can manage this condition and improve patient outcomes.[22] This study aimed to compare the efficacy and safety of two Unani formulations, Safoof Darchini and Safoof Muhazzil, in the management of obesity, focusing on their impact on body weight, body mass index (BMI), waist circumference, lipid profile, and overall health improvements in obese patients.

In this randomized, single-blind comparative clinical trial, we assessed the clinical outcomes of Safoof Darchini and Safoof Muhazzil, two herbal formulations used in traditional Unani medicine for managing obesity. The study included 60 obese participants who were randomly assigned to either the test group (Safoof Darchini) or the control group (Safoof Muhazzil). After a treatment period of 90 days, we evaluated both subjective and objective parameters to determine the effects of the treatments. The results of this trial demonstrated significant improvements in the test and control groups across several parameters. Both Safoof Darchini and Safoof Muhazzil were found to effectively reduce body weight, BMI, waist circumference, and serum lipid levels, indicating their potential as anti-obesity agents. These findings are consistent with the traditional use of these formulations, which are known for their calorific, deobstruent, and metabolic-boosting properties. Furthermore, all participants in both groups were advised to follow dietary restriction (≤1300 kcal/day) and regular exercise (20–30 minutes of brisk walking daily). Adherence to these lifestyle interventions was not objectively quantified or controlled through dietary logs, physical activity monitoring, or compliance scoring. Given that structured caloric restriction and exercise alone are known to produce significant weight loss and metabolic improvements, it is difficult to isolate the independent pharmacological contribution of the study drugs from the lifestyle-induced effects. Therefore, the improvements observed may reflect a combined lifestyle and pharmacological effect rather than a robust drug-specific action.

Cinnamon powder has garnered attention in recent years for its potential anti-obesity effects.[23] This traditional spice,

commonly used in both culinary and medicinal contexts, contains several bioactive compounds, most notably cinnamaldehyde, which are believed to contribute to its beneficial impact on body weight and metabolic health.[24] Research has suggested that cinnamon can influence various pathways involved in glucose and lipid metabolism, making it a potential therapeutic agent for obesity management.[25]

One of the primary mechanisms through which cinnamon exerts its anti-obesity effects is by enhancing insulin sensitivity.[26] Insulin resistance is a hallmark of obesity, leading to elevated blood glucose levels and increased fat storage.[27] Cinnamon has been shown to improve insulin sensitivity, allowing for more efficient glucose utilization and reducing the storage of excess fat in the body.[28] This effect may be mediated through cinnamaldehyde, which activates key signaling pathways involved in insulin action, such as the AMP-activated protein kinase (AMPK) pathway.[29] AMPK activation helps to increase glucose uptake and fatty acid oxidation, both of which contribute to a reduction in body fat.[30]

In addition to improving insulin sensitivity, cinnamon powder also plays a role in regulating lipid metabolism.[31] Studies have shown that cinnamon supplementation can lead to reduced levels of total cholesterol, low-density lipoprotein (LDL) cholesterol, and triglycerides, while promoting an increase in high-density lipoprotein (HDL) cholesterol.[32] This favorable lipid profile is important for reducing the risk of cardiovascular diseases, which are often associated with obesity.[33] The modulation of lipid metabolism by cinnamon is thought to be partly due to its antioxidant properties, which help to reduce oxidative stress and inflammation in adipose tissue, thereby improving fat metabolism.[34]

Cinnamon may also promote weight loss by stimulating thermogenesis, the process by which the body generates heat and burns calories.[35] Cinnamaldehyde has been shown to increase the activity of brown adipose tissue (BAT), a type of fat that burns energy to produce heat.[36] This thermogenic effect contributes to an increase in energy expenditure, which helps to reduce overall body fat.[37] Additionally, cinnamon's ability to improve gut microbiota composition may play a role in weight management by supporting healthier digestion and nutrient absorption, which can further contribute to weight loss.[38]

Furthermore, cinnamon's anti-inflammatory and antioxidant properties play a crucial role in combating obesity-related complications.[39] Chronic inflammation is commonly seen in obese individuals and is associated with insulin resistance, metabolic dysfunction, and the accumulation of visceral fat.[40] Cinnamon's polyphenolic compounds have been shown to exert anti-inflammatory effects by inhibiting pro-inflammatory cytokines and reducing oxidative stress, both of which are implicated in the pathogenesis of obesity.[41] By mitigating these harmful effects, cinnamon helps to restore metabolic balance and prevent obesity-related health issues.[42]

Despite these promising findings, the evidence supporting cinnamon's efficacy as an anti-obesity agent is still evolving. While some clinical trials have demonstrated significant reductions in body weight and improvement in metabolic parameters with cinnamon supplementation, others have shown modest or no effects. The variability in results may be attributed to factors such as the form of cinnamon used (Cinnamomum cassia vs. Cinnamomum verum), dosage, and the duration of supplementation. Further well-designed, large-scale clinical trials are needed to confirm cinnamon's effectiveness and establish optimal dosing guidelines for obesity treatment. In contrast, Safoof Muhazzil is a polyherbal formulation comprising ingredients such as Zeera Siyah (Carum carvi), Ajwain (Trachyspermum ammi), Marzanjosh (Origanum majorana), Badiyan (Foeniculum vulgare), Luk Maghsool (Cocos lacca), Bura Armini (Sodium borate), and Suddab (Ruta graveolens). These components are traditionally described as Muhazzil (anti-obesity), Musakhkhin (calorific), Mudir (diuretic), and Mulattif (demulcent) agents. Experimental studies have suggested that Safoof Muhazzil possesses antioxidant, anti-inflammatory, and lipid-lowering activities, which may contribute to weight reduction through mechanisms distinct from those attributed to cinnamon. The potential synergistic effects of multiple phytoconstituents in this formulation could explain its efficacy in improving metabolic parameters.[17,18]

In terms of safety, both treatments were well-tolerated by participants, with no significant adverse events reported. The absence of major side effects highlights the safety profile of these Unani formulations, supporting their use as alternative or adjunct therapies for obesity management. While both formulations showed effectiveness in treating mild to moderate obesity, neither was effective in cases of morbid obesity.

One of the key strengths of this study is its comparative design, which allows for a direct comparison between two widely used Unani formulations. The use of objective measures such as BMI, waist circumference, and lipid profile provides robust evidence of the efficacy of these treatments. Additionally, the study's inclusion of a control group enhances the reliability of the results and helps to mitigate bias.

However, this study has certain limitations that should be considered. The sample size was relatively small, with 30 participants in each group, which may affect the generalizability of the results. Furthermore, the study duration was limited to 90 days, and long-term outcomes or potential relapse after treatment cessation were not evaluated. Future studies with larger sample sizes and longer follow-up periods are recommended to confirm these findings and explore the long-term safety and efficacy of Safoof Darchini and Safoof Muhazzil.

CONCLUSION

The results of this clinical trial suggest that both Safoof Darchini and Safoof Muhazzil are effective and safe in managing obesity. These formulations offer promising alternatives in the treatment of obesity, especially for

individuals seeking complementary therapies. Further research with a larger cohort and extended follow-up periods is warranted to establish their long-term efficacy and potential integration into mainstream obesity management strategies.

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CONFLICT OF INTEREST

The authors state that there is no conflict of interest.

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