Clinical Efficacy of a Unani Formulation in the Treatment of *Saman-e-mufrat* (Obesity)

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Abstract

randomized single blind placebo controlled trial was designed to evaluate the efficacy of Unani formulation viz *Ajwain desi/ Nankhwah* (*Trachyspermum ammi* L.), *Tukhme Suddab* (*Ruta graveolens* L.*), Zeera Siyah/Kamoon* (*Carum carvi* L.), *Marzanjosh* (*Origanum majorana* L.), *Bura Armani (Armeniac bole)* in the patients of *Saman-e-Mufrat* (Obesity). Total 30 patients were allocated randomly to Test and Control groups and were treated with Unani formulation and with placebo respectively for the period of 60 days. All the Patients were advised planned diet and 30 minutes brisk walk daily for the same duration and they were assessed for subjective and objective parameters. The data was statistically analyzed by Repeated Measures ANOVA with post test and Tukey-Kramer multiple comparison test, One-way ANOVA and Friedman test.

A significant improvement in intra group comparison was noted in objective parameters, (Body weight, Body Mass Index, Upper Arm Circumference, Waist Hip Ratio, Skin fold thickness). In inter group comparison the effect on UAC and WHR were significant while effect on body weight, BMI and Skin fold thickness was statistically not significant. The study revealed that the test drug is safe and effective for the management of obesity.

Key word: Obesity, *Saman-e-mufrat,* Body Mass Index, *Trachyspermum ammi* L.*, Ruta graveolans* L.*, Carum carvi* L.*, Origanum majorana* L.*, Arminiac bole.*

Introduction

Saman-e-mufrat (obesity) is one of the commonest and most prevalent diseases of affluent society of the world. The prevalence of obesity is consistently increasing day by day. It has become global epidemic and contributes to increasing burden of type-2 diabetes mellitus, cardiovascular diseases, hypertension, stroke, and eventually causing premature death worldwide. (Humes *et al.,* 2000; Mohan, 2005; Bray, 2004) Nevertheless, obesity epidemic is an actual and potential public health problem and possesses pronounced economic health consequences. Earlier, it was considered a state of excess adipose tissue mass or characterized by excessive accumulation of fat in the subcutaneous and deep tissue of the body, usually 20% or more of an individual's ideal body weight. (Longo *et al.,* 2012; Longe, 2005) But it is now defined in terms of the body mass index (BMI = weight in kilograms divided by height in meters square) and if BMI is

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greater than 25 kg/m^2, the person is considered to be overweight and if it is greater than 30 kg/m^2 the patients is called obese. (Longo *et al.,* 2012; Longe, 2005; Humes *et al.,* 2000; Neinstein, 2002; Souhami *et al*., 2002; Siegenthaler, 2007) over weightness/Obeseness (*Saman-e-mufrat*) result from an imbalance between energy intake and its expenditure. (Ferri *et al.,* 2012; Warner, 2003)

Historically, Greco Arab Physicians like *Buqrat* (Hippocrates), *Jalinoos, Ibn sina, Zakariya Razi, Ibn Nafis, Daud Intaki* and *Akbar Arzani* were well acquainted with *Saman-e-mufrat* and they have mentioned it in their treatises enormously in terms of its etiological factors, symptoms, signs, and complications. (Ibn Sina, 1929; Halim, 2005; Razi, 1991; Jurjani, 1996; Chandpuri, 1998; Antaki, 2010)

Ibn Sina especially pointed out that obese people are more prone to develop cardiac and cerebral complication like stroke, syncope, coma, palpitation, breathlessness, concealed haemorrhage and sudden death. (Ibn Sina, 1929; Halim, 2005) As per Unani philosophy *Saman-e-mufrat* develops due to increased *barid Akhlat* (cold humors) leading to imbalance in body humours resulting tendency to accumulate the *Akhlate fasida* particularly *maddae balghamiya* on different parts of the body. (Kabeeruddin, 2001)

The aim of treatment of obesity is to reduce body weight, Modification in risk factors such as decreasing daily calorie intake, increase physical activity and behavioural therapy are the non-pharmacological measure to achieve the goal. Indeed, life style modification is helpful for most obese patients, but in several circumstances pharmacological management of obesity is inevitable. Sibutramine (Fetergil/Leptos) Orlistat (Cobese/Lipocut), Rimonabant (Riomont/ Zimult), Diethylepropion (Anorex/Tapanil), are widely prescribed drugs in main stream of medicine. (Laurence *et al.,* 2006) But the long term use of these drugs produce several side effects. Sibutramine produces hypertension, tachycardia, headache, insomnia, constipation and dry mouth etc. Orlistat are reported to produce incontinence of urine, flatulence, and vitamins malabsorption and Rimonabant is reported to demonstrate adverse effects like nausea, dizziness, anxiety, and depression. (Laurence *et al.,* 2006). Therefore, long term use of these drugs could not possible. Bariatric surgery is recommended for the patients of morbid obesity but it also exhibited several post operative complications such as malabsorption, malnutrition and vitamins deficiency etc. Furthermore, it is quite painful procedure and associated with risks of infection, large disfiguring skin, depression and formation of blood clots eventually lead to dangerous circulatory problem and kidney failure. (Townsend, 2008)

Owing to high prevalence, multi factorial causes and life threatening complications of the disease and most importantly, the inability of contemporary system of medicine to deliver safe and effective drug management of obesity, warrants search of alternative treatment to alleviate such complex diseases of serious complications.

Unani system of medicine has a large number of single and compounds drugs which possess actions like *muhazzil* (Emaciatic), *muhallil* (Resolvent)*, mudir* (Diuretic)*, musakhkhin* (Endothermic) are being in use to the management of *Saman-e-mufrat* since ancient period. Some studies carried out in recent past demonstrated promising result and explored the potentiality of Unani drugs to be used as effective anti obesity agent. Now a days, the researchers have taken interest to investigate drugs with an aim to provide better alternate in the currently available drugs.

In view of above facts, a compound formulation which is recommended by *Ismail Jurjani* in *Zakhira khawarzam shahi* for the treatment of obesity, containing *Ajwain desi* (seed of *Trachyspermum ammi* L.), *Tukhme Suddab* (seeds of *Ruta graveolens* L.)*, Zeera siyah* (seeds of *Carum carvi* L.), *Marzanjosh* (*Origanum majorana* L.), *Bora Armani* (*Armeniac bole*) has been selected for study. (Jurjani, 1996) The ingredients of test formulation are endowed with *haar yabis* temperament and possess properties like *Mohazzil, Musakhkhin*, *Hazim, mushile balgham, Mulattif, and Mudir* etc. and it ameliorate the derangement of temperament leading to minimize *fasad* in *maddae bhalghamia* and is being effective in obesity.

As this combination appears to be quite rational in term of ingredient having actions warranted in the treatment of obesity, and has been in use by Unani physicians since long time but the efficacy of this time tested formulation has not been scientifically evaluated so far. Therefore, a single blind placebo controlled study was envisaged to find out efficacy of combination in the management of obesity on scientific parameters.

Methodology

The present clinical study was conducted in Department of Moalajat, National Institute of Unani Medicine Bangalore, from September 2010 to February 2012. Prior to the beginning of clinical trial, the research protocol was submitted to Ethical committee of National Institute of Unani Medicine and Ethical clearance was obtained from the committee. During screening a total of 44 patients were registered for the study but 7 patients did not fulfil inclusion criteria hence

excluded from the study and remaining 37 patients were randomly allocated into test and placebo groups. Four patients from test group and three patients from placebo group were lost to follow up, leaving behind 20 patients in Test and 10 patients in Placebo group who completed the course of treatment.

Patients fulfilling the inclusion criteria were provided an information sheet having details concerning the nature of the study, the drug to be used with the mode of administration and method of treatment. Patients were given sufficient time to go through the contents of informed consent sheet. The patients were left free to ask whatever the query regarding the study and if they agreed to be enrolled in the study, they were requested to sign the informed consent form. The patients who did not fulfil inclusion criteria were excluded from the study.

The blue print of the study was conceptualized in material and methods which can be described under few headings for convenient comprehension.

1. Criteria for selection cases

   a) Inclusion criteria

   - Patients with *Saman-e-mufrat* (Obesity) of either sex.
   - Patients belonging to 15-60 years of age.
   - Patients having BMI between 25- 35kg/m^2.
   - Patient able to participate in the study and ready to follow the instructions and sign the consent form.
   - Obese patients having associated symptoms like restricted movement, joints pain, Weakness and letharginess, Dyspnoea, and Palpitation.

   b) Exclusion criteria

   Physiological status

   - Patient below the age of 15 and above the age of 60.
   - Pregnant and lactating women.

   Pathological status

   - Patients having cardiovascular disease, severe renal disease and severe hepatic disease and hypothyroidism.
   - Patients having BMI > 35 kg/m^2.

- Patients who refuse to give the written informed consent for the study.

2. Selection of subjects

Known cases of *Saman-e-mufrat*, having the symptoms like increasing body weight, restricted movement, joints pain, breathlessness and palpitation etc. were taken up from OPD and IPD section of NIUM hospital and subjected to lab investigations.

3. Investigations

Investigations like Lipid Profile, Haemoglobin percent, Total Leucocyte Count, Differential Count, Kidney and Liver function tests were done in all patients before starting the trial and also after completion of the study. However thyroid profile, Fasting & Post Prandial blood sugar and ECG were done prior to start the trail to exclude the patients suffering from other diseases.

4. Study design

The study was designed as a randomized single blind placebo controlled clinical study.

5. Sample size

The sample size was fixed as 30 patients.

6. Duration of protocol therapy

The treatment period in both Test and Placebo groups was fixed as 60 days.

7. Test drugs

The ingredients of test drugs are as follows:

1.	*Ajwain desi* (*Trachyspermum ammi* L.)	1 part
2.	*Tukhme Suddab* (*Ruta graveolens* L.)	1 part
3.	*Zeera siyah* (*Carum carvi* L.)	1 part
4.	*Marzanjosh* (*Origanum majorana* L.)	4 parts
5.	*Bora Armani (Armeniac bole)*	4 parts

8. Method of preparation, dosage and mode of administration of Test drug

Good quality single drugs were obtained from the pharmacy of National Institute of Unani Medicine, Bangalore. Before preparing the formulation, the drugs were properly identified to ascertain their originality. The ingredients were cleaned by weeding out unwanted material and separated impurities, and then powdered.

9. Administration of Test drug &placebo

The Test drug was administered orally in Group-A in the dosage 5gm once a day with cane vinegar 7.5ml just after breakfast for the period of two months. The placebo (containing wheat floor) was given in Group B in the dosage of 5 gm once a day just after breakfast for the period of two months. Along with the drugs, all the patients (in both groups) were recommended 1200-1800 k cal/day diet and also advised moderate physical exercise (20-30 minutes brisk walk) during the course of the study. (Longo *et al.,* 2012)

10. Follow up during treatment

Sixty days study was divided into 4 visits as follow up which were made at an interval of 15 days each. At every visit, patients were asked about the progression or regression in their symptoms and were subjected for examination to assess clinical findings.

11. Efficacy assessment

The assessment of efficacy in the test and placebo groups was based on subjective and objective parameters. Subjective parameters include symptoms like, restricted movement, joints pain, weakness & letharginess, dyspnoea and palpitation. Objective parameters are anthropometric measurements and laboratory investigations of the patients suffering from *Saman-e-mufrat*. Both subjective and objective parameters were assessed at every visit, while lipid profile was carried out before and after the completion of trial.

As subjective parameters differ in severity from patient to patient, therefore an arbitrary grading scale Total Sign and Symptom Score (TSSS) were adopted for appropriate assessment and statistical evaluation. The severity of 5 different signs and symptoms (Restriction of movement, Joints pain, Weakness & letharginess, Dyspnoea, Palpitation) were rated on a 4 point scale (0, absent; 1, mild; 2, moderate; 3, severe).

After the completion of treatment, the pre and post treatment values or scores of different parameters (subjective and objective) were assessed and were subjected to comparison and statistical analysis.

12. Objective Parameters

- Weight in kilogram
- Body mass index (BMI)
- Skin fold thickness.
- Upper arm circumference.
- Waist and hip ratio.
- Lipid profile.

13. Withdrawal criteria

a) Patients who fail to follow the protocol

b) Any adverse reaction or adverse event noticed by the patients/ investigators

c) Patients who were drug defaulters.

14. Safety Assessment

In order to assess safety of test drug LFT, RFT, Haemogram (Hb%, TLC, DLC & ESR) were carried out before and after treatment in both groups.

(a) Criteria for safety evaluation

No occurrence of any adverse effect or reaction during the treatment period.

(b) Adverse drug reaction documentation

Any adverse event or reaction appearing during the study either in Test or Placebo group was recorded.

15. Documentation

The case report forms and consent forms properly documented throughout the study and were submitted to the Deptt. of *Moalajat* after completion of the study.

16. Statistical analysis

At the end of study all the results were tabulated and statistically analyzed by Friedman test,

Kruskal-Wallis test with Dunn's multiple comparison tests repeated major ANOVA, one-way ANOVA with post test, Tukey-Kramer multiple comparison test and paired t test.

Results

Demographic data and effect of Test drug and Placeboon subjective parameters are depicted in Table (1) & (2).

Body weight

The mean score of body weight, in placebo group was 77.12 kg on 0 day, 76.86 on 15th day, 76.41 kg on 30th day, 76.13 kg on 45th day and 75.76 kg on 60th day, whereas in test group it was 80.5 kg on 0 day, 79.36 kg on 15th day, 78.44 kg on 30th day, 77.34 kg on 45th day and 76.37 kg on 60th day of treatment. (Table 3) In placebo group it was significant on 30th day with respect to day 0 ($p<0.01$), on 45th day with respect to day 15 ($p<0.01$) and on 60th day with respect to day 30($p<0.05$) and in Test group it was extremely significant on 15th day ($p<0.001$) with respect to 0 day, whereas it was not significant in inter group comparison ($p>0.05$). However, the body weight was reduced in both groups.

Body Mass Index

The mean of BMI of Placebo group was 31.08 kg/m^2 on baseline, 30.98 kg/m^2 on 15th day, 30.80 kg/m^2 on 30th day, 30.68 kg/m^2 on 45th day and 30.52 kg/m^2 on 60th day, whereas in Test group it was 30.56 kg/m^2 on 0 day, 30.11 kg/m^2 on 15th day, 29.77 kg/m^2 on 30th day, 28.9 kg/m^2 on 45th day and 28.97 kg/m^2 on 60th day of treatment (Table 3). In placebo group it was significance 30th day ($p<0.05$) with respect to day 0, on 45th day ($p<0.05$) with respect to day 15th and on 60th day ($p<0.05$) with respect to day 30th. In Test group it was significant on 45th day ($p<0.001$) with respect to test day 0, on 45th day ($p<0.001$) with respect to day 15th, on 45th day ($p<0.05$) with respect to test day 30th. The Inter group comparison was not significant ($p>0.05$).

Upper Arm Circumference

The mean UAC of placebo group was 31.28 cm. on baseline, 31.25 cm. on 15th day, 31.0 cm on 30th day, 30.75 cm. on 45th day and 30.6 cm. on 60th

day. Whereas, in test group UAC was 32.3 cm. on 0 day, 31.75 cm. on 15th day, 31.01 cm. on 30th day, 30.46 cm. on 45th day and 29.85 cm. on 60th day of treatment (Table No.-3). In placebo group it was significant on 45th day ($p<0.05$) with respect to day 0, on 60th day ($p<0.01$) with respect to day 15th, In test group significant on 15th day ($p<0.01$) with respect to test day 0, on 30th day ($p<0.001$) with respect to test day 15th, on 45th day ($p<0.01$) with respect to test day 30th, on 60th day ($p<0.01$) with respect to test day 45th. The Inter group comparison was also significant ($p<0.05$).

Waist Hip Ratio

The mean of WHR in placebo group was 1.01 on baseline, 1.01 on 15th day, 1 on 30th day, 0.99 on 45th day and 0.98 on 60th day. Whereas, in Test group, mean WHR was 1.02 on 0 day, 1 on 15th day, 0.97 on 30th day, 0.94 on 45th day and 0.93 on 60th day of treatment (Table No.-3). In placebo group it was significant on 45th day ($p<0.01$) with respect to placebo day 0, on 45th day ($p<0.05$) with respect to placebo day 15th, In test group significant on 30th day ($p<0.01$) with respect to test day 0, on 45th day ($P<0.001$) with respect to test day 15th, on 60th day ($p<0.01$) with respect to test day 30th. The Inter group comparison was also found significant ($p<0.05$).

Skin Fold Thickness

The mean of skin fold thickness in placebo group was 96.9 mm on baseline, 96.4 on 15th day, 94.8 mm on 30th day, 93.1 mm on 45th day and 91.6 mm on 60th day. Whereas, in test group skin fold thickness was 105.67 mm on 0 day, 102 mm on 15th day, 97.62 mm on 30th day, 94 mm on 45th day and 91.42 mm on 60th day of treatment (Table No.-3). In placebo group it was significant on30th day ($p<0.05$) with respect to placebo day 0, on 45th day ($p<0.001$) with respect to placebo day 15th and on 60th day ($p<0.001$) with respect to placebo day 30th. In test group, it was significant on 15th day ($p<0.001$) with respect to test day 0, on 30th day ($p<0.001$) with respect to test day 15th, on 45th day ($p<0.001$) with respect to test day 30th, and on 60th day ($p<0.001$) with respect to test day 45th. The Inter group comparison was not significant ($p>0.05$).

Serum Cholesterol

The baseline mean value of serum cholesterol was 185.95 mg/dl in test group and 180.8 mg/dl in placebo group. After completion of treatment mean value of serum cholesterol was observed 192.55 mg/dl in test group and 196.8 mg/dl in placebo group. For statistical analysis paired t test for intra group comparison

was done, significant ($p<0.05$) improvement was observed in placebo group with respect to day 0, but in test group it was found not significant. ($p>0.05$) Kruskal-Wallis post test with Dunn's Multiple pair comparison test was done for inter-group comparison, no significant improvement ($p>0.05$) was observed in test group. (Table No.-4)

Serum Triglycerides

The baseline mean value of serum triglycerides was 147.35 mg/dl in test group and 151.3 mg/dl in placebo group. After completion of treatment mean value of serum triglycerides was observed 128.35 mg/dl in test group and 159.9 mg/dl in placebo group. For statistical analysis paired t test for intra group comparison was done, no significant ($p>0.05$) improvement was observed in placebo group but it was not quite significant in test group ($p=0.057$). Kruskal-Wallis post test with Dunn's Multiple pair comparison test was done for inter-group comparison, no significant improvement was observed ($p>0.05$) (Table 4).

HDL-Cholesterol

The baseline mean value of HDL-Cholesterol was 41.25 mg/dl in test group, and 40.2 mg/dl in placebo group, after compilation of treatment mean value of HDL-Cholesterol 41mg/dl in test group and 39mg/dl in placebo group. For statistical analysis paired t test for intra group was done, no significant improvement was observed in placebo group and test group ($p>0.05$). One-way ANOVA comparison test was done for inter group comparison, no significant improvement was observed ($p>0.05$) (Table 4).

Safety Studies

In the study safety parameters (Haemogram, TLC, DLC, ESR, LFT & RFT) were also assessed before and after the treatment. The safety markers were remained normal before and after treatment. (Table 5)

Table 1 : Demographic Data of patients in Test and Placebo group n = 30

	n	Fp%		N	Fp%
Age group			Dietary Habit		
15-29	15	50%	Vegetarian	5	16.6%
30-44	14	46.6%	Mixed Diet	25	83.3%
45-60	1	3.3%			
Gender			Family History		
Male	19	63.3%	Positive	19	63.3%
Female	11	36.6%	Negative	11	36.6%
Marital status			Duration of Illness		
Married	29	80%	0-4 years	22	73.3%
Unmarried	6	20%	5-8 years	4	13.3%
			9-12 years	4	13.3%
Socioeconomic Status*			Mizaj		
Grade-I	1	3.3%	Balghami	24	80%
Grade-II	10	33.3%	Damvi	6	20%
Grade-III	19	63.3%	Safravi	0	0%
Grade-IV	0	0%	Saudavi	0	0%

(*According to Kuppa Swami Scale)

Table 2 : Effect of Test drug and Placebo on Subjective Parameters

(Test group n = 20, Placebo group n = 10)

Parameters	Group	0 day	15 days	30 days	45 days	60 days
Restriction of movement	Placebo	2 (0,2)	2 (0,2)	2 (0,2)	2 (0,2)	1 (0,2)
	Test	2 (1,3)	2 (1,3)	1(1,2)	1(0,2) a, b	0 (0,1) a, b, c, d, e, f, g
Joints pain	Placebo	2 (1, 3)	2 (1, 2)	2 (1, 2)	1 (1, 2)	1 (0, 2)
	Test	2 (1, 3)	2 (1, 3)	2 (1, 2)	1 (0, 2) a, b, d	0 (0,1) a, b, c, d, e, f
Weakness and lethargy	Placebo	2 (1, 3)	2 (1, 3)	2 (1, 3)	1 (1, 2)	1 (1, 2)
	Test	2 (1, 3)	2 (1, 3)	2 (1, 3)	1 (0, 2) a, b, c	1 (0, 2) a, b, c, d, e, f
Dyspnoea	Placebo	1.5 (1,3)	1.5 (1, 3)	1 (1, 2)	1 (1, 2)	1 (0, 2)
	Test	2 (1, 3)	1 (1, 2)	1(0, 2)	1 (0, 1) a	0 (0, 1) a, b, c, d, e, f, g
Palpitation	Placebo	1 (0, 2)	1 (0, 2)	1 (0, 2)	1 (0, 2)	0 (0, 1) a
	Test	1 (1, 2)	1 (1, 2)	1 (0, 2)	(0, 1) b, c	(0, 1) b, c, d, e

P<0.01 with respect to test day 0, b- P<0.01 with respect to test day 15,
P<0.01 with respect to test day 30, d- P<0.001 with respect to placebo day 0,
P<0.001 with respect to placebo day 15, f- P<0.001 with respect to placebo day 30,
P<0.001 with respect to placebo day 45.

Table 3 : Effect of Test Drug Formulation on Objective Parameters

(Test group n = 20, Placebo group n = 10)

Parameters	Group	0 day	15 days	30 days	45 days	60 days
Weight	Placebo	77.12 ± 2.01	76.86 ± 1.98	76.41 ± 2.03a	76.13 ± 2.08a, b	75.76 ± 2.15a, b, c
	Test	80.5 ± 2.51	79.36 ± 2.54d	78.44 ± 2.50d	77.34 ± 2.46d	76.37 ± 2.49 d
BMI	Placebo	31.08 ± .67	30.98 ± .68	30.80 ± .69a	30.68 ± .69a, b	30.52 ± .67a, b, c
	Test	30.56 ± .41	30.11 ± .42	29.77 ± .43	28.9 ± .60d, e, f	28.97 ± .42d, e, f
UAC	Placebo	31.28 ± .53	31.25 ± .53	31 ± .48	30.75 ± .52a	30.6 ± .55a, b
	Test	32.3 ± .46	31.75 ± .45c	31.01 ± .46c, d	30.46 ± .48c, d, e	29.85 ± .48c, d, e, f, g
WHR	Placebo	1.01 ± .02	1.01 ± .02	1 ± .02	0.99 ± .02 a, b	0.98 ± .02a, b
	Test	1.02 ± .02	1 ± .017	0.97 ± .016c	0.94 ± .016c, d	0.93 ± .015c, d, e, f
Skin fold thickness	Placebo	96.9 ± 4.018	96.4 ± 4.13	94.8 ± 4.07a	93.1 ± 4.04a, b	91.6 ± 4.03a, b, c
	Test	105.67 ± 3.54	102 ± 3.42d	97.62 ± 3.4d, e	94 ± 3.53d, e, f	91.42 ± 3.46d, e, f, g

a. <0.05 with respect to placebo day 0,
b. P<0.01 with respect to placebo day 15,
c. <0.01 with respect to test day 0,
d. P<0.001 with respect to test day 15,
e. P<0.01 with respect to test day 30,
f. P<0.01 with respect to test day 45.
g. P<0.001 with respect to test day 45.

Table 4 : Effect of Test drug and Placebo on Lipid profile

	Group	B.T.	A.T.
Serum Cholesterol	Placebo	180.8±6.79	196.8±9.48a
	Test	185.95±6.76	192.55±7.22b
Serum Triglyceride	Placebo	151.3±20.81	159.9±22.76a
	Test	147.35±11.23	128.35±8.59b
HDL- Cholesterol	Placebo	40.2±1.51	39±1.19a
	Test	41.25±1.34	41±1.59b

a. P<0.05 with respect to placebo day 0, b. P<0.001 with respect to placebo day 15

Table 5 : Safety Assessments for Test

(n = 20) Placebo group (n = 10), Baseline vs. 60th day

Parameters		Test group		Placebo group	
		BT	AT	BT	AT
		Mean ± SEM	Mean ± SEM	Mean ± SEM	Mean ± SEM
Hb%		12.86 ± 0.48	12.92 ± 0.45	13.03 ± 0.586	11.9 ± 0.735
TLC		12302 ± 3840.8	8457.5 ± 388.54	9160 ± 708.04	8240 ± 384.19
DLC	P	57.1 ± 1.478	56.6 ± 2.65	58.1 ± 2.04	58.1 ± 2.04
	L	36.75 ± 1.515	37.2 ± 2.37	35.9 ± 1.88	35.9 ± 1.88
	E	3.75 ± 0.279	4 ± 0.333	3.6 ± 0.221	3.6 ± 0.221
	M	2.4 ± 0.245	2.3 ± 0.36	2.4 ± 0.16	2.4 ± 0.16
	B	0 ± 0.00	0 ± 0.00	0 ± 0.00	0 ± 0.00
ESR		22.2 ± 2.88	22.7 ± 3.68	20.3 ± 2.82	18.2 ± 4.96
AST		30.4 ± 3.59	26.2 ± 2.23	27.2 ± 4.69	26.8 ± 3.88
ALT		24.4 ± 1.93	20.9 ± 1.13	21.5 ± 2.40	21.4 ± 2.36
S. Creatinine		0.835 ± 0.031	0.835 ± 0.027	0.81 ± 0.03	0.82 ± 0.02
Blood Urea		21.3 ± 1.138	22.5 ± 1.087	23.1 ± 1.64	24.7 ± 1.96

Discussion

Obesity is a disease of imbalance between energy intake and energy expenditure resulting in fat deposition inside the body which is responsible for various pathological changes and eventually causes ischemic heart disease, hypertension, diabetes mellitus, mild exertional dyspnoea, osteoarthritis etc. The treatment of obesity therefore mainly revolves around the management of weight reduction. According to Unani philosophy the main culprit of *Saman-e-mufrat* is *ijtemae akhlate ghleeza* (accumulation of morbid humours) leading to derangement of temperament particularly due to *ghalbae balgham*.Hence, any drug which possesses properties like *Muhallil, Muhazzil, Mullattif, Mudir, Qatae bhalgham, Qatae Akhlate ghaleeza* can ameliorate the derangement of temperament by evacuating *fasid maddae bhalghamia* and thereby effective in the management of obesity.

The administration of Test drug brought about significant reduction in the subjective and objective parameters consorted with the patients of obesity, demonstrating that the test combination is effective in relieving the symptoms associated with obesity and reducing body weight. These effects are

probably due to the diverse action of ingredients of Test formulation. Some of the ingredients of the test drug have been reported to possess important pharmacological actions that directly or indirectly support our contention regarding efficacy of test drug. *Ajwain desi* (*Trachyspermum ammi* L.), *Tukhme Suddab* (*Ruta graveolens* L.*), Zeera siyah* (*Carum carvi* L.), *Marzanjosh* (*Origanum majorana* L.), *Bora Armani* posses diverse pharmacological action like *Muhallil, Muhazzil, Mullattif , Mudir, Qatae bhalgham and Qatae akhlate ghaleeza* and endowed with *haar yabis* (hot & dry) (Ibn Baitar, 2000; Ibn Sina, 1929; Najm-ul-Ghani, 1927; Kabeeruddin, 2010; Ibn-ul-Quff, 1986). Thus these drugs act in the same line that has been mentioned above, in ameliorating symptoms of obesity.

It appears that the combined effect of the different constituents of the test drug produced anti obesity effect and or the combined effect of the constituents of the test drug modified the disease process, consequently improved various symptoms of obesity. As a result body weight, body mass index, upper arm circumference, skin fold thickness and waist hip ratio showed improvement up to some extent. An improvement in almost all the subjective as well as objective parameters clearly indicated anti obesity effect of Test drug. It is likely that, the different properties of ingredients of the test drug may have complemented each other to make suitable changes in the adipose tissues to improve its functioning. The effect on reducing body weight in placebo group may be due to strict dietary restriction and moderate exercise which was advised in both groups. Further, in test group more significant improvement was due to action of ingredients of test formulation, particularly the *Muhazzil*, and *Qatae balgham* effect of *zeera siyah*, (Najm-ul-Ghani, 1927; Ghulam Nabi, 2007) *Muhallil* effect of *tukhame suddab* (Ibn Sina, 1929; Ibn Ibrahim Magharibi, 2007), *Mulattif* action of *Marzanjoosh* (Ibn Hubal Baghdadi, 2005, Najm-ul-Ghani, 1927) and *Qateh akhlate ghaleeza* properties of *Bora Armani* (Ibn Baitar, 2000; Ibn Sina, 1929; Kabeeruddin, 2007; Najmul Ghani, 1927; Ibn-ul-Quff, 1986). The varied properties of above drugs complement each other and facilitate the anti obesity effect of test formulation.

Conclusion

In the present study, test drug exhibited overall improvement in the symptoms of the disease and was found effective in the management of Obesity without demonstrating any adverse effects as the safety markers (Haemogram, LFT and RFT) were remained within limit after completion of the course of the treatment.

On the basis of above result and discussion, it can be concluded that Unani formulation *Ajwain desi* (*Trachyspermum ammi* L.), *Tukhme Suddab* (*Ruta graveolens* L.)*, Zeera* siyah (*Carum carvi* L.), *Marzanjosh* (*Origanum majorana* L.), *Bora Armani* (*Armeniac bole*) is quite effective and safe in the treatment of *Saman-e-mufrat*. However, other aspect of Test formulation should also be explored, so that untapped potential of the test drug could be utilized to provide complete and safe remedy for treatment of *Saman-e-mufrat* (Obesity).

Acknowledgment

The authors are thankful to the authorities of National Institute of Unani Medicine Bangalore, for providing financial assistance and facilities for clinical trial.

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