

# An alternative approach to treat obesity with leptogenic polyherbal formulation obeseure: A randomized clinical trial study

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**Abstract:** Obesity is a common disease of developing countries, including Pakistan. Obesity is a risk factor for many diseases which can be life threatening or making the person unable to perform daily routine work. In the current study, clinical trials were designed to evaluate the effects of medical intervention by comparing the effects of placebo control drug “Plasicure” with the herbal medicinal formulation “Obeseure”. The test drug formulation was designed on the basis of the screening study for Leptogenic drugs. To evaluate the safety of the test drug, the toxicity index and the safety profile of test formulation was assessed on animal models. The drug was found safe for further clinical study. Randomized Controlled Clinical Trials were conducted. The statistical analysis was carried out by the application of Two-Way Repeated Analysis of Variance test. The clinical findings of randomized controlled trial revealed that the test drug was Leptogenic and effective in weight reduction as compared to control drug Plasicure therapy as the p-value deduced was 0.001 in leptin level and 0.000 in case of BMI after the conduction of Two-Way Repeated Analysis of Variance test. Hence it is concluded that obeseure therapy is more significant than control drug Plasicure therapy in the management and treatment of obesity.

**Keywords:** Obesity, leptin, herbal drugs, toxicity, clinical trials.

## INTRODUCTION

Obesity is a Medical condition which is continuously expanding worldwide and causing serious medical sicknesses (Hales, *et al.*, 2020). Individuals are considered obese when their Body Mass Index (BMI) is more than 30 kg/m<sup>2</sup>. The prevalence of obesity in young adults is 15% (Hales, *et al.*, 2020), for men 28% and for women 38 %, which is a big gap between the two genders. Obesity is increasing in urban population (56% in men and 67% in women) as compared to rural population. Obesity in youth is also increasing at higher rate. Worldwide prevalence of obesity is tripled from 1975-2016. Overweight and obesity are linked to more deaths worldwide than underweight (Siddiqui, *et al.*, 2018)

According to the World Health Organization’s Global Health Observatory (GHO) data, the prevalence of obesity both in men and women aged 18 and over was 39% while children and adolescents were 18% in 2016. The plague of obesity is spreading at an unprecedented pace reaching at an epidemic proportion, particularly in urban areas of middle-income countries. In the United States, 60% of the adults are currently either obese or overweight (Lim, *et al.*, 2020).

Obesity is considered to be a result of increased caloric intake and decreased expenditure. Therefore, physical activity with a calorie restriction, remains the main principle of treatment in obese persons (Blüher, 2019).

Attraction to unhealthy diets, high in carbohydrates and fatty acids, is rising in middle income countries. Busy schedules and sedentary lifestyles with increased automated work are contributing to the trend of decreased physical activity. It is suggested that, as long as culture and environment support unhealthy lifestyle patterns, especially through media, modifying lifestyle would be unattainable (Booth, 2011).

Increased public awareness regarding obesity-related health problems, along with the social pressure concerning the body image and a desire to have a slim body, has enormously given way to alternative medicines during the recent years (Schutz, *et al.*, 2019).

Some patients need anti-obesity medications which for which exercise and diet are not viable options. Some weight loss medications are stimulants for limited usefulness with many other unwanted effects. Orlistat reduces intestinal fat absorption including cases of severe liver injury reported rarely after using this medicine. Sibutramine is an anorectic and may increase blood pressure causing dry mouth, constipation, headache

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and insomnia. Consequently, alternative methods have replaced the standard weight-lowering methods with proven efficacy (Volkow, *et al.*, 2017).

Leptin hormone is considered to be the good option to increase energy dissipation and suppression of appetite to reduce weight (Lund, *et al.*, 2020). It is one of the most significant fat inferred hormones. Leptin stimulates receptors present in the nerve cells of the brain, where it suppresses appetite, checking the impacts of neuropeptide Y (an intense appetite stimulant discharged by cells in the gut and in the nerve of the brain) and balancing the impacts of anandamide (another powerful sustaining appetite stimulant that attaches to indistinguishable receptors from THC) (Ueno and Nakazato, 2016). The absence of leptin (or its receptor) prompts uncontrolled food consumption and causing obesity. Some research studies have demonstrated that fasting or following a low-caloric diet (VLCD) brings down leptin levels (Ng, 2017). Leptin levels change more when intake of nutrition decreases. The positive connection between muscle to fat ratio mass and serum leptin is likely clarified fundamentally by the high release of leptin for huge contrasted and fewer fat cells (Dallner, *et al.*, 2019). Leptin discharge per gram of fat tissue is multiple times more significant in obese than in lean subjects. Since fat cell size is normally extended 2–4 times in the obese, when communicated per fat cell, leptin discharge is up to multiple times higher in fatter than in lean subjects. Likewise, an expanded number of fat cells, especially in outrageously obese, without a doubt add in increments in serum leptin (Arabi, *et al.*, 2020). Plasma leptin levels increase in weight put on and decrease with weight reduction, steady with leptin's job as a sign of the size of fat tissue stores (Li, *et al.*, 2017). Numerous cutting-edge modes are, practically speaking, to direct the leptin levels in human body, yet these applies some genuine side effects. So as to defeat this issue, there is an incredible need to locate some restorative plants having leptin guideline properties which can be utilized in the decrease of weight in obese people.

In the present research study, an endeavor was made to assess the therapeutic effects of plants having leptin regulating properties to decrease weight in obese people by planning a polyherbal formulation.

## **MATERIALS AND METHODS**

### ***Plant materials Collection and authentication of drugs***

The plants *Caralluma fimbriata* dried extract, *Saussurea costus* roots, *Delphinium denudatum* roots and *Cassia fistula* dried legumes were selected from literature search with sufficient relevancy of anti-obesity effects and were purchased from Herbal Store, Faisalabad. The purchased medicinal plants were identified and authenticated by Dr. Iqbal Hussain from Department of Botany, GCUF under voucher number 112.

All the medicinal plants were sorted and sifted for contamination, dust and soil. All the drugs were reduced to small pieces through crusher and cutter machines. All the drugs were made into powder through grinding machine. The powder was packed into food grade containers with proper labeling.

### ***Alcoholic extraction process***

The powdered drugs were soaked in 1000ml methanol for 48 hours with continuous stirring after 5-hour interval. After soaking, the drugs were filtered with cotton and Whatman filter. The filtrate was concentrated on a rotary evaporator. The remaining wet contents were evaporated in water bath for 48 hours. The dried extract was stored in airtight containers and kept at 4°C temperature (Valsalam, *et al.*, 2019).

### ***Screening of drugs having leptogenic effects***

Serum Leptin level was a parameter to identify the drug, whether it can be associated with an increase in leptin level (Leptogenic) or decrease in leptin level (an obesogenic). Four drugs; *Caralluma fimbriata*, *Saussurea Costus*, *Delphinium denudatum* and *Cassia fistula* were screened out in experimental trials on mice and formulated as “Obesecure” for further clinical trials.

### ***Acute toxicity evaluation***

In acute toxicity study all the animals were given different doses of polyherbal formulation between 1000mg to 5000mg/kg of the body weight. The animals were observed for 72 hours and were checked after an interval of every 30 minutes both in terms of biochemical and behavioral parameters by following the study of (El Kabbaoui, *et al.*, 2017).

### ***Subacute toxicity evaluation***

#### ***Hematological parameters***

All the hematological parameters like HGB, RBC, MCH, RDW, HCT, MCHC, MCV, MPV, WBC, MON, NEU, LYM, PLT were analyzed on automatic hematology analyzer (Prabu, *et al.*, 2013).

#### ***Biochemical parameters***

Biochemical parameters like creatinine, Urea ALT and AST, was evaluated in test and control groups through clinical chemistry analyzer (Porwal, *et al.*, 2017).

#### ***Histopathological study***

Liver and the Kidney samples were preserved in buffered formalin. The organs were embedded in paraffin and cut into 5-micron slices to be observed under light microscope.

### ***Clinical Efficacy of herbal coded formulation (Obesecure)***

#### ***Study design***

The current study is a case control, multicenter, double blind, prospective randomized authentic Placebo

controlled, two arm parallel group clinical trials. Laboratory investigations such as leptin level was conducted at baseline and then eight weeks after treatment to assess the level of leptin. The patients were checked by General physician and given the test drug (Obesecure) and control drug (Plasicure) for obesity. The enrolled patients were grouped in two categories, i.e. test group and control group. The test group was administered polyherbal formulation obesecure, that was formulated by different medicinal plants. The control group was administered Plasicure capsule. A total number of 132 participants of both sexes coming the OPD were enrolled in the study according to the inclusion criteria. Only those patients were included in the study who were willing to sign the consent form. Man or woman aged 20 to 50 years with a BMI more than 25 kg/m<sup>2</sup>, married and unmarried, taking no anti-obesity drugs were included. Pregnant, hypertensive, chronic liver disease, hormonal therapy taking and diabetic patients were excluded from the study. Patients withdrawn were those who were not willing to continue, patients suffering from any systemic disease during treatment were withdrawn from study.

Trials were conducted on approximately 132 patients from both groups (66 patients from the control and 66 from experimental group) between ages of 20-50 years regardless of socioeconomic status. After the diagnosis of participants, the participants were randomly separated into two groups of 66 each. Patients in Group 1 (control group) were prescribed Plasicure Capsule 500mg twice and those in Group 2 (Test group) were prescribed obesecure 500mg capsule twice daily for three months. Short term efficacy was measured by improvement in symptoms at the follow up visit after one week and the long-term efficacy was assessed by the remarked weight loss in one month of the second visit.

The patient's serum was tested by using ELIZA assays with 96 well microplate on Biotech 800 absorbance reader. The Data was recorded, fed on MS Excel worksheet and imported into SPSS for further statistical analysis. All the data were analyzed using SPSS version 23. The clinical evaluation included the improvement in abdominal stiffness, body weight, appetite, bowel habits. Likert scale was used to analyze the intensity of symptoms (scored as severe: 3, moderate: 2, mild: 1 and absent: 0) after 2 weeks and after 4 weeks of treatment. Interquartile ranges (IQR) and Median values were recorded to represent the level of improvement. The side effects were recorded during therapy. Liver function test, lipid profile, leptin level, blood complete examination and urine complete examination were also being examined at baseline and after treatment to analyze and record any drug adverse action on these systems. Data was collected by the filling of clinical trial proforma through personal interview, use of case records, personal observation file and other relevant documents. The data were collected

from April 2015 to March 2018. BMI and leptin level tests are considered as key tests for the study.

#### ***Ethical issues and approval of clinical trials***

The research study was approved by the Ethical Review Committee of Faculty of Eastern Medicine, Hamdard University, Karachi, Pakistan and Ethical review Board of GC University Faisalabad. The study is also registered internationally in clinical trials. Gov. with NCT04443790 clinical trial identification number.

#### ***Diagnostic technique***

Patients having BMI more than 25 were clinically examined by taking a complete history, general physical examination, Triceps Skin Diameter and Waist circumference. A clinical trial proforma was filled consisting of patient's biodata, clinical features and investigation. The patient consent form was filled before the initiation of treatment and repeatedly filled up during the course of treatment

#### **STATISTICAL ANALYSIS**

Pre and Post data of test drug and control drug was analyzed using two-way Repeated Measures analysis of variances. A Variable; visits, is defined by two factors 1 and 2 where 1 shows the pre-treatment test (Baseline) and 2 shows the follow up (follow-up) for both treatments.

#### **RESULTS**

##### ***Preclinical toxicity study results***

###### ***Acute toxicity effects***

It was noted that the drug showed no toxic effects and no abnormal behavioral sign in clinical and biochemical parameters at the maximum dose of 2000mg/kg of the test drug. The level of LD50 of polyherbal drug was seen more than 2000mg/kg/day (table 1).

###### ***Subacute toxicity effects***

It was observed that the drug showed no toxic effects on hematological parameters (table 2). No change in the biochemical parameters is noted after 28 days of observation.

###### ***Clinical trials results***

The primary outcome of this research study was to elevate the level of leptin resulting in suppression of appetite and decrease in weight. Secondary outcome was to decrease the signs and symptoms of obesity complications. A data of 132 patients collected and frequency of male patients was 53 while female patients was 79.

###### ***Patient characteristics***

The mean ages and standard deviations of patients being prescribed the test drug formulation "Obesecure" as calculated were 31.59 ±0.92. The mean age of participants prescribed control drug Plasicure treatment as calculated was 30.4 ±0.98 as shown in Graph 1.

### **Analysis of drugs effects on leptin, weight and BMI levels**

In test drug (Obeseure) group, 91% patients showed increased leptin level in follow up tests as compared to baseline tests while 9% patients showed no change in the level of leptin after treatment. In control drug (Plasicure) group, 42% patients showed increased leptin level and 23% patients showed decreased leptin level in follow up tests as compared to baseline tests while 35% patients showed no change in the level after treatment.

In test drug (Obeseure) group, 91% patients showed an increased BMI level of follow up tests as compared to baseline tests while 9% patients showed no change in the level of BMI after treatment. In Control drug (Plasicure) group, 41% patients showed an increased BMI level and 15% patients showed decreased BMI level of follow up tests as compared to baseline tests while 44% patients showed no change in the level after treatment.

The descriptive statistics of all patients for each group is given in table 06. The results show that the follow up reading of Test Group is showing higher change (Mean=0.222 with a deviation of 0.0904) in the leptin level as compared to follow up reading of control group (Mean=0.1808 with a deviation of 0.0885).

The results show that the follow up reading of BMI Test Group is showing minimal change (Mean=31.26 with a deviation of 2.48) in the BMI level as compared to follow up reading of control group (Mean=32.42 with a deviation of 2.06).

### **Treatments**

Estimated marginal means with S.E and the pairwise comparison of both treatments were shown in table 05. The difference between the means of control treatment and test treatment is significant at the 5% level of significance. Test treatment has a higher mean of leptin as compared to control treatment.

### **Visits**

Estimated marginal means with S.E and the pairwise comparison of both visits were shown in table 6. The difference between the means of control treatment and test treatment is significant at the 5% level of significance. Control treatment has a higher mean of leptin as compared to test treatment.

### **Treatment \* Visits**

The interactive effect of Treatment\*Visit shows the overall model of significance. The overall model is significant at the 5% level of significance for leptin study table 7. Treatment 1 (Test) and Treatment 2 (Control) have almost same mean of the Leptin level at baseline reading while treatment 1 is showing significant increases

in leptin level in follow-up reading (Profile Plots and Graph 1)

## **DISCUSSION**

The results of our study indicate that polyherbal formulation Obeseure is nontoxic and safe to use for weight reduction and appetite control. The drug is nontoxic and safe to be used in further clinical trials (table 3). No change in the organs was observed. The organs showed no histological change in the slides. The drug has no toxic effects on the organs. Which means that test drug is effective to increase the level of leptin for energy dissipation and weight loosening which means that test drug is effective to decrease the Body Mass Index. The higher mean of leptin in test treatment at follow up readings indicate that the drug is effective and producing leptogenic effects. Clinically, it has been noted that patients felt appetite suppression and no weakness amid treatment. The formulation showed good results in phlegmatic disorders like malaise, post nasal drip, body aches, flu, weakness, indigestion and even better results in libido. The test drug has decreased weight as compared to control drug without having any adverse effects on liver functions, kidney functions and other unusual clinical changes. The study has revealed that test drug formulation obeseure has good results in regular bowel evacuation habits.

Test drug formulation Obeseure is well effective due to pregnane glycosides of *Caralluma fimbriata*, which have energy boosting, weight loosening, blood sugar reducing, sperm producing, kidney function improving, muscle building, vessels softening and brain function improving effects. Flavonoid derivatives have a bowel regulating and tumor dissolving effects. Costunolide have anti-inflammatory, antitumor, anticancer, immunomodulatory, hypolipidemic and hypoglycemic effects (Rasul *et al.*, 2012).

Previously, it has been reported that fennel and cumin as supplements may ameliorate sperm quality of obese animals following weight loss and reduction in leptin concentration. The decrease in leptin concentration is directly proportional to fat storage. Fennel and cumin have no direct effects on leptin pathways (Nejatbakhsh, *et al.*, 2017). Test drug formulation Obeseure has obvious effect on leptin pathways as it increases the let-in level with a decrease in weight. In another study an herbal combination KBH-1 was used which exhibited alleviating effects by improving steatosis in liver and leptin resistance by up-regulating the activation of AMPK and suppressing the expression of PPAR $\gamma$ . These findings showed the potential of herbal combination KBH-1 as a functional food supplement or preventive agent in the treatment of obesity (Lee, *et al.*, 2016) but the mechanism as combination is not well defined.

**Table 1:** Observations (Macroscopic and General behavioral) of acute toxicity study of control and test drug treated groups.

Observations	Normal (0mg/kg)	1000mg/kg	2000mg/kg	3000mg/kg	4000mg/kg	5000mg/kg
Food consumption	No Variation	No Variation	No Variation	Reduced	Reduced	Reduced
Water Consumption	No Variation	No Variation	No Variation	Raised	Raised	Raised
Eyes color	No Variation	No Variation	No Variation	No Variation	No Variation	Normal
Mucus secretion	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Sedation	Not observed	Not observed	Not observed	Not observed	Not observed	Not observed
Fecal Color	No Change	No Change	No Change	No Change	No Change	Normal
Convulsion	Not Observed	Not Observed	Not Observed	Not Observed	Not Observed	Not Observed
Drowsiness	Not Observed	Not Observed	Not Observed	Not Observed	Not Observed	Not Observed
Diarrhea	Not Observed	Not Observed	Not Observed	Not Observed	Occurred	Occurred
Skin change	No Change	No Change	No Change	No Change	No Change	Normal
Coma	Not observed	Not observed	Not observed	Not observed	Not observed	Not observed
Urination	No Change	No Change	No Change	No Change	No Change	Normal
Loss of life	No death	No death	No death	No death	No death	Alive

**Table 2:** Subacute effects of orally administered test drug formulation Obesecure on hematological parameters

Parameter	Normal (0mg/kg)	500mg/kg	800mg/kg	1000mg/kg
Total RBC (106/ $\mu$ L)	8.430 $\pm$ 0.276	7.126 $\pm$ 0.342	5.896 $\pm$ 1.109	8.703 $\pm$ 0.739
HGB(g/L)	13.734 $\pm$ 0.896	9.901 $\pm$ 0.405	8.866 $\pm$ 1.906	12.267 $\pm$ 1.691
MCHC (g/dL)	34.401 $\pm$ 1.645	31.701 $\pm$ 0.681	34.101 $\pm$ 1.059	32.901 $\pm$ 1.007
HCT (%)	41.266 $\pm$ 2.640	31.100 $\pm$ 0.862	25.966 $\pm$ 5.852	37.500 $\pm$ 4.158
MCH (pg.)	15.633 $\pm$ 0.352	15.433 $\pm$ 0.466	15.666 $\pm$ 0.384	16.366 $\pm$ 0.569
MCV (fL)	42.566 $\pm$ 0.425	44.066 $\pm$ 0.581	44.100 $\pm$ 0.929	45.033 $\pm$ 0.578
RDW (%)	15.034 $\pm$ 0.727	12.467 $\pm$ 1.042	13.734 $\pm$ 0.769	14.667 $\pm$ 0.867
PLT (103/ $\mu$ L)	798.334 $\pm$ 134.192	745.667 $\pm$ 70.966	587.334 $\pm$ 81.686	632.001 $\pm$ 79.432
Monocyte (%)	3.801 $\pm$ 0.643	2.501 $\pm$ 0.417	2.601 $\pm$ 0.703	2.867 $\pm$ 0.657
Lymphocyte (%)	89.101 $\pm$ 0.578	75.934 $\pm$ 2.785	76.834 $\pm$ 3.332	88.201 $\pm$ 3.838
Neutrophil (%)	20.834 $\pm$ 1.141	18.467 $\pm$ 2.311	19.167 $\pm$ 5.504	21.167 $\pm$ 2.863
WBC (103/ $\mu$ L)	13.601 $\pm$ 1.116	12.134 $\pm$ 0.677	10.934 $\pm$ 1.408	10.334 $\pm$ 2.719
MPV (fL)	8.567 $\pm$ 0.318	8.967 $\pm$ 0.546	10.967 $\pm$ 2.373	10.834 $\pm$ 1.683

Values are expressed as mean  $\pm$  SEM (n=5). P > 0.05 when compared to the normal group.

**Table 3:** Subacute effects of orally administered test drug formulation Obesecure on serum biochemical parameters (per kg Body weight)

Parameter	Normal 0mg	500mg	800mg	1000mg
Creatinine(mg/dl)	0.367 $\pm$ 0.032	0.401 $\pm$ 0.058	0.334 $\pm$ 0.034	0.434 $\pm$ 0.034
SGPT (ALT) (U/L)	28.667 $\pm$ 2.729	45.334 $\pm$ 4.911***	56.001 $\pm$ 2.082***	58.667 $\pm$ 2.849***
SGOT (AST) (U/L)	131.001 $\pm$ 13.278	213.334 $\pm$ 12.667*	202.334 $\pm$ 8.413*	218.667 $\pm$ 28.789*
Urea (mg/dl)	22.767 $\pm$ 2.052	22.834 $\pm$ 0.822	27.034 $\pm$ 2.067	28.301 $\pm$ 2.194

Values are shown as mean  $\pm$  SEM

**Table 4:** Descriptive statistics of pre-treatment and follow ups

Groups	Measures	Baseline readings (1)			Follow up readings (2)		
		Mean	Std. Deviation	N	Mean	Std. Deviation	N
Test Group	Leptin	.1809	.0883	66	.222	.0904	66
	Weight	103.71	9.43	66	100.39	9.71	66
	BMI	32.30	2.34	66	31.26	2.48	66
Control Group	Leptin	.1817	.0968	66	.1808	.0885	66
	Weight	100.98	7.94	66	101.39	8.69	66
	BMI	32.30	1.94	66	32.42	2.06	66

**Table 5:** Marginal means and pair comparison of treatment for leptin, weight and BMI

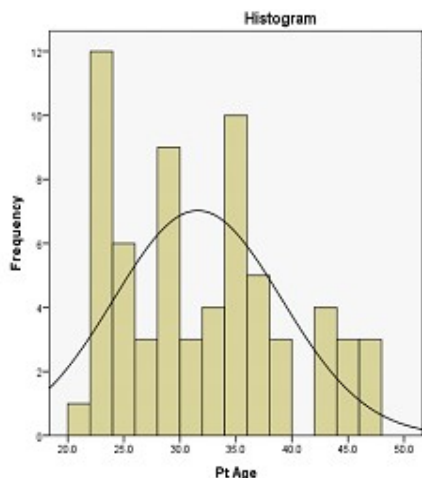
	Treatment	Mean	Std. Error	95% Confidence Interval		Mean Diff. (I-J)	Sig.
				Lower Bound	Upper Bound		
Leptin	1 (Baseline)	0.181	.010	.161	.202	0.020*	0.001
	2 (Follow-up)	0.201	.011	.180	.223		
Weight	1 (Baseline)	102.05	1.169	99.719	104.387	0.864	0.046
	2 (Follow-up)	101.18	1.018	99.156	103.223		
BMI	1 (Baseline)	32.364	.244	31.877	32.851	0.580	0.000
	2 (Follow-up)	31.784	.293	31.199	32.369		

**Table 6:** Marginal means and pair comparison of visits for leptin, Weight and BMI

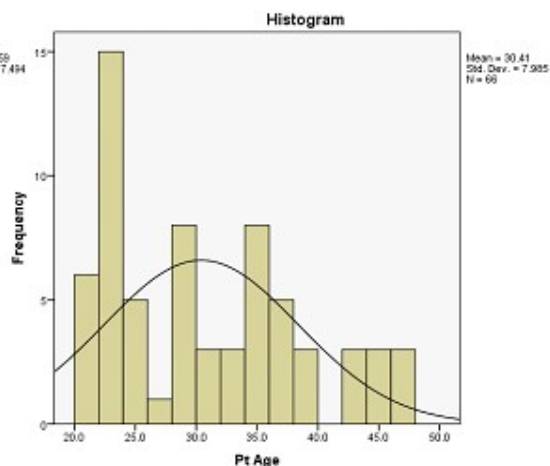
	Visit	Mean	Std. Error	95% Confidence Interval		Mean Diff.(I-J)	Sig.
				Lower Bound	Upper Bound		
Leptin	1 (Baseline)	0.181	0.01	0.161	0.202	0.020*	0.001
	2 (Follow-up)	0.201	0.011	0.18	0.223		
Weight	1 (Baseline)	102.34	1.052	100.247	1.455	1.455	0.000
	2 (Follow-up)	100.89	1.107	98.683	-1.455		
BMI	1 (Baseline)	32.304	.260	31.784	32.823	0.460	0.000
	2 (Follow-up)	31.844	.272	31.300	32.388		

**Table 7:** Marginal means of treatment-visits for leptin

	Treatment	Visits	Mean	Std. Error	95% Confidence Interval	
					Lower Bound	Upper Bound
Leptin	1 (Test)	1 (Baseline)	0.181	0.011	0.159	0.203
		2 (Follow-up)	0.222	0.011	0.200	0.244
	2 (Control)	1 (Baseline)	0.182	0.012	0.158	0.206
		2 (Follow-up)	0.181	0.011	0.159	0.203
Weight	1 (Test)	1 (Baseline)	103.71	1.161	101.392	106.032
		2 (Follow-up)	100.39	1.196	98.005	102.783
	2 (Control)	1 (Baseline)	100.98	.977	99.033	102.937
		2 (Follow-up)	101.39	1.070	99.257	103.531
BMI	1 (Test)	1 (Baseline)	32.303	.288	31.728	32.878
		2 (Follow-up)	31.265	.305	30.655	31.875
	2 (Control)	1 (Baseline)	32.305	.239	31.828	32.782
		2 (Follow-up)	32.424	.254	31.917	32.930



Histogram with Normal Curve of Test Group Age



Histogram with Normal Curve of Control Group Age

The study conducted by Yuliana has condensed all works concentrated on screening plant materials by focusing on significant pathways identified by the vitality admission guideline, either by *in vivo* or *in vitro* tests. The customary conviction that homegrown medication is more secure than engineered ones are one of the old-style contentions, albeit logically this isn't in every case genuine (for an example prohibition on Ephedra).

In any case, when all is said in done, it has been generally recognized that a plant compound, with its one of a kind platforms and rich decent variety is a boundless wellspring of novel lead mixes (Yuliana, *et al.*, 2011).

The study of Blom was a creature model for the craving suppressant impact assurance of *Hoodia gordonii*. They examined hunger stifling properties and related metabolic impacts. Sustenance consumption, administrative peptides and biochemical changes affirm its anorectic activity (Blom, *et al.*, 2011).

The test drug formulation obese definition depends on leptin level in serum. The medications having impact to build the leptin levels were chosen and defined to expand vitality dispersal and decline vitality consumption. Our examination has likewise recommended that test drug formulation Obese potentially affects weight reduction and leptin level. Leptin level is legitimately corresponding to fat tissue stockpiling so it demonstrated an expanded level in tissue serum in the underlying phases of weight reduction with continuous abatement later on.

## CONCLUSION

The clinical findings of randomized controlled trial revealed that the test drug Obese is effective at 500mg twice a day in the treatment of obesity. The effect was significant as compared to control drug in obesity management by increasing the leptin level; however, it is not well defined whether Obese also reduces the resistance of leptin or not. In the future studies the leptin and glucose resistance aspects will be considered to see the antidiabetic effects also. There was no untoward manifestation associated with the test drug Obese and found good in the treatment of Obesity and its associated symptoms. The acute and sub-acute toxicity study of polyherbal formulation on experimental animals is safe at a dose of 2000mg/kg/day.

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