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TESTOFEN™

HUMAN CLINICAL TRIAL

Brief of the Study :

Total Participants : 60

Participants on Active (TESTOFEN) : 30. 29 of them completed the study

Participants on Placebo : 30. 26 of them completed the study.

Dosage used : 600 mg of TESTOFEN per day, 300 mg in the morning and 300 mg in the evening.

Duration of study : 8 Weeks

Objective of the study:

To determine the effects of the ingestion of TESTOFEN on

- INCREASE IN LEVELS OF FREE TESTOSTERONE
- BODY COMPOSITION

Participants : Male aged 18-35 years, trained for resistance/power exercise, at least for a period of 1 month

Background

Physical fitness and use of various therapies for it is discussed very often these days. To attain it, daily physical exercise is a must, which helps to build good muscle strength and endurance. If the routine exercise regime is supported with some dietary supplements, it improves the muscle strength and endurance to a greater extent.

Fenugreek contains the steroidal saponins, sapogenins and furostanol saponins , which are important precursors for the synthesis of a number of sex hormones. Animal studies indicate that fenugreek increases free testosterone secretion in the body. Increased testosterone levels can lead to improved body composition (increased lean body mass, enhanced muscles, diminished visceral fat), mood and cognition.

TESTOFEN is a product containing fenugreek seed extract as an active ingredient.

Animal studies conducted in rats have established safety and efficacy of TESTOFEN.

Increase in the weight of the seminal vesicles, ventral prostrate and musculus levator ani was observed with the use of TESTOFEN. Increase in the weight of the seminal vesicles and ventral prostrate indicates androgenic activity whereas increase in the weight of musculus levator ani indicates anabolic activity.

TESTOFEN was well tolerated by animals.

Efficacy and safety of fenugreek in human beings is established in conditions like diabetes and dyslipidemias by various clinical trials.

Formulation of TESTOFEN

Fenugreek seed was ground into a powder and was extracted using hydro-alcohol and a proprietary process of extraction. Thereafter, it was spray dried into a powder. Each Capsule contained 300-mg of TESTOFEN- fenugreek seed extract.

Objectives of the trial

This trial is designed to explore the efficacy and safety of TESTOFEN in healthy male volunteers doing regular resistance exercise. Primary objectives of the study were to determine the effects of TESTOFEN on free testosterone and body composition during eight weeks of resistance exercise and to evaluate safety of TESTOFEN.

Method for evaluation

Thirty subjects with following inclusion and exclusion criteria received TESTOFEN.

Inclusion criteria

Subjects to be enrolled in the trial have to meet ALL of the following criteria:

- Written informed consent from the subject.
- Male aged 18-35 years inclusive.
- Normal health status on the basis of clinical examination
- Normal health status on the basis of laboratory examination
- Trained for resistance/power exercise, at least for a period of 1 month

Exclusion criteria

Subjects will be excluded for ANY ONE of the following reasons:

- Subjects with any condition which in the opinion of the investigator makes the subject unsuitable for inclusion.
- Subject has an elevated resting heart rate (>100 bpm) or blood pressure (SBP ≥140 or DBP ≥90 mm Hg).
- Subject has a history of medical or surgical events that may affect the study outcome or place the subject at risk, including cardiovascular disease, gastrointestinal problems, metabolic, renal, hepatic, neurological or active musculoskeletal disorders.
- Subject has a history of orthopedic injury or surgery within the last year.
- Known hypersensitivity to herbal drugs/nutritional supplement/ foods
- Subjects who is consuming/ has received any performance enhancing therapy during last 2 months
- Subjects undergoing any weight loss or diet plan during the trial period
- Chronic alcoholics
- Drug abusers
- Participation in any other clinical trial during last 30 days
- Simultaneous participation in another clinical trial.

Dosage :

Eligible subjects consumed 2 capsules of TESTOFEN, one in the morning and one in the evening, for 8 weeks. Each Capsule contained 300-mg of fenugreek seed extract. . Subjects were evaluated 3 times during the trial period (Visit 1: Day –3 to -1, Visit 2:day 0, Visit 3:day 56).

Subjects did not take any performance enhancing therapy during the trial period and 2 months before starting the trial.

Results

Out of 30 enrolled subjects on active group, one discontinued the study and was not included in analysis. Out of 30 subjects in the placebo group, four discontinued the study and were not included in the analysis. The mean age of the subjects was 23.21 years and average height was 165.52 cm.

Body weight : NO CHANGE in body weight and BMI

Pre-treatment body weight (kg)	64.93
Post treatment body weight (kg)	64.90

There was no significant change in the body weight after 8-week consumption of fenugreek extract. BMI remained same

The study has shown improvement in following parameters after 8-week consumption of TESTOFEN ™.

1.] Free Testosterone

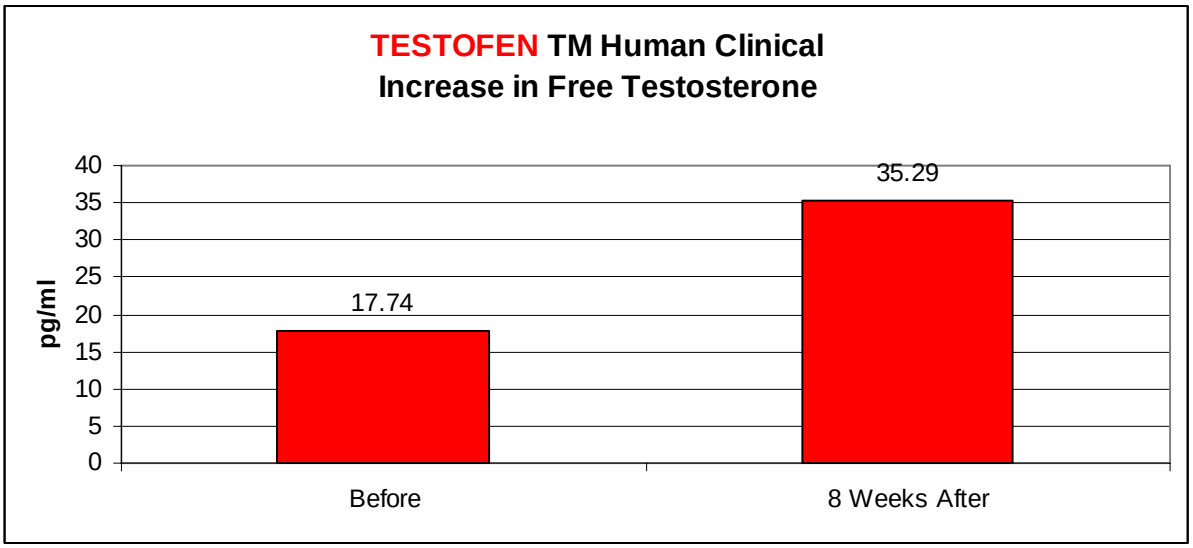
Free Testosterone levels in serum were estimated before and after 8-week consumption of TESTOFEN.

Free testosterone levels before and after treatment (pg/ml) :

Results	Free testosterone pg/ml
Pretreatment levels	17.76
Post treatment levels	35.29
Total Increase	17.55
% of Increase	98.81 %

Rise in free testosterone produced by TESTOFEN was quite significant. The results clearly indicate that TESTOFEN has positive effects on the biologically active free testosterone secretion.

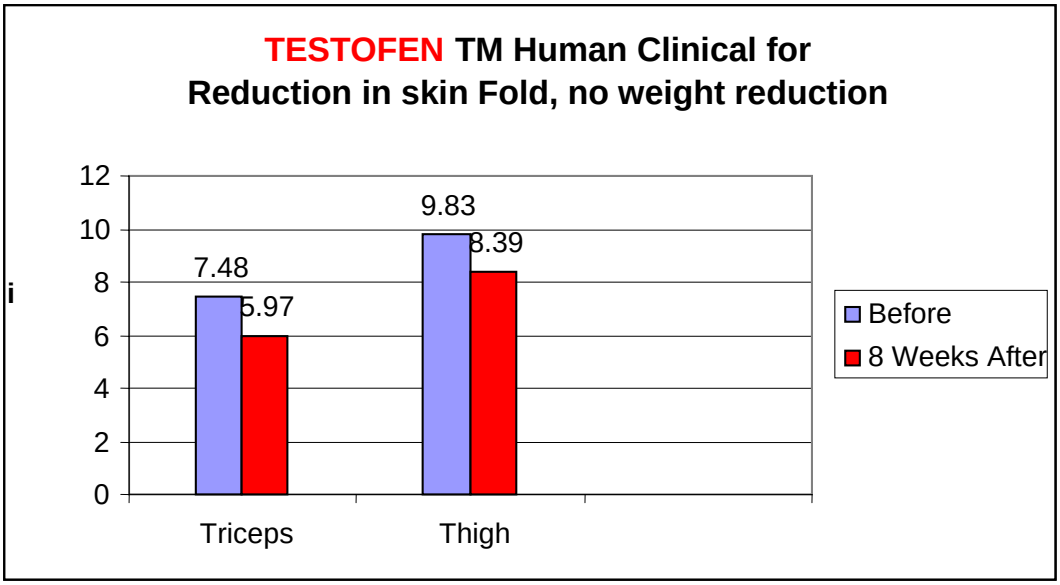
The increase in Free Testosterone levels in active group of participants was 100% more than the increase of Free Testosterone Levels in the placebo group.


TESTOFEN TM Human Clinical
Increase in Free Testosterone
pg/ml
40
35
30
25
20
15
10
5
0
17.74
35.29
Before
8 Weeks After

2.] Body Composition :

Skin fold thickness was measured at the triceps and thighs before and after administration of TESTOFEN.

	Triceps	**Thigh**
Pretreatment skin fold thickness (mm)	7.48	9.83
Post treatment skin fold thickness (mm)	5.97	8.39
Reduction in Skin Fold	1.51	1.44
% of Reduction	20.18 %	14.64 %



Reduction in skin fold thickness after 8-week consumption of TESTOFEN was significant in the thigh and biceps regions. It clearly indicates the favorable impact of TESTOFEN on skin fold thickness. In spite of reduction in skin fold thickness there was no reduction in body weight. Reduction in skin fold thickness indicates a direct reduction in body fat. This confirms that the loss of weight by decrease in skin fold thickness is compensated by increase in muscle mass. The placebo group did not show significant reductions compared to active.

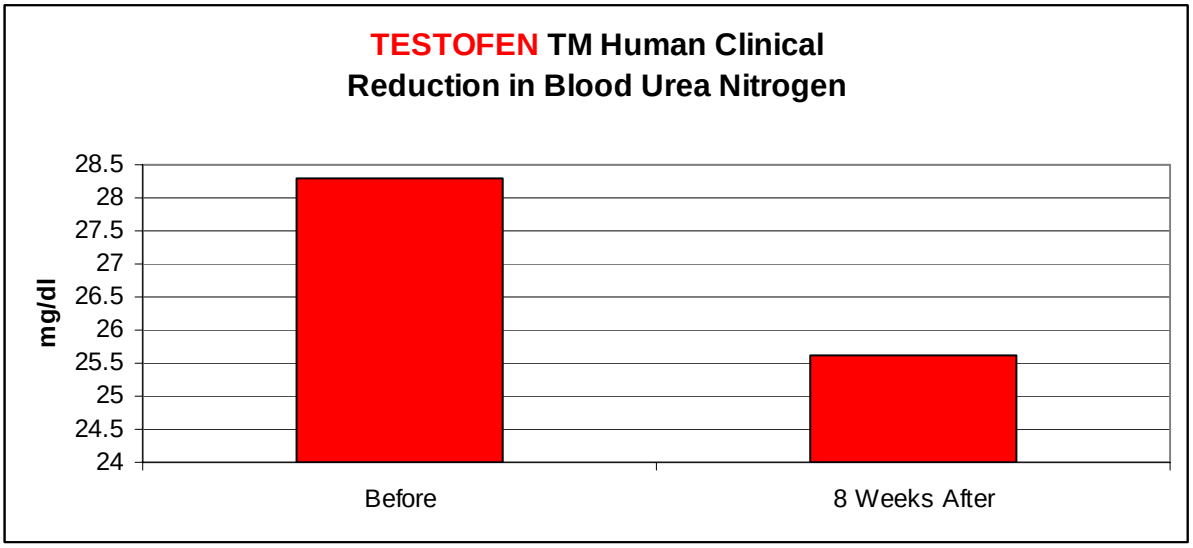
3.] Blood Urea Nitrogen - Proves Reduction in Protein Catabolism

Blood Urea Nitrogen assessment of all subjects was done before and after the treatment.

Results	BUN mg/dl
Pretreatment levels	28.28
Post treatment levels	25.62
Reduction in Blood Urea Nitrogen	- 2.66
% of Reduction	9.40 %

Blood Urea nitrogen levels were significantly reduced after 8-week consumption of TESTOFEN. This reflects reduction in protein catabolism. This parameter confirms muscle mass build up during the study while skin fold decrease took place. The BUN levels of the placebo group were unchanged.

Figure 5: Blood Urea Nitrogen levels before and after treatment (mg/dl)



Conclusion of the 60 patients Human Clinical trial :

It appears that 300 mg twice a day consumption of TESTOFEN coupled with physical activity and exercise has a favorable impact on increasing free testosterone levels significantly.

Safety :

The following biochemical parameters were analysed for the active and placebo groups

Heart Rate
Blood Glucose Levels
Body Temperature
Blood Pressure
Respiratory Rates
Alkaline Phosphate
Bilirubin [Total, Direct and Indirect]
Creatinine
Haemoglobin
Haematocrit
MCV
MCHC
RBC Count
WBC Count
Platelets
Lymphocytes
Monocytes
Basophils
Eosinophils
Neutrophils

All the parameters were normal for all participants.