Testofen®

Human Clinical Study for Free Testosterone & Muscle Mass Boosting

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HUMAN CLINICAL TRIAL REPORT

EFFECT OF TESTOFEN® ON SAFETY, ANABOLIC ACTIVITY AND FACTORS AFFECTING EXERCISE PHYSIOLOGY

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AIM: Effect of TESTOFEN® on Safety, Anabolic Activity and factors affecting Exercise Physiology.

STUDY DESIGN: A prospective, double-blind, randomised, placebo controlled study.

STUDY DURATION: 8 weeks

CLINICAL END POINTS (ASSESMENT)

I. **PRIMARY** -To determine the effect of TESTOFEN® on Safety, Anabolic Activity, Blood Testosterone, Immune Function during 8 weeks of intense resistance exercise.

II. **SECONDARY**- To determine the effects of TESTOFEN® on body composition, Creatinine, Prolactin, and Muscle mass variation.

MEDICATION DETAILS:

TESTOFEN® (Fenugreek extract powder):

Pharmaceutical form: Capsules-- 300mg

Active ingredient: Extract of Fenugreek

PLACEBO:

Pharmaceutical form: Capsules-300mg

Placebo ingredient: Di Calcium Phosphate

TREATMENT SCHEDULE / DOSE:

Volunteers were advised to take two capsules per day: one capsule 20 minutes before breakfast and another capsule 20 minutes before dinner.

POPULATION/DEMOGRAPHY:

Sixty (60) healthy males trained at least for a period of one month for resistance exercise and who are eligible as per the inclusion and exclusion criteria will be included in the study.

PRIOR TREATMENT DETAILS: Study population was comprised of healthy volunteers with no history of previous treatment.

SELECTION CRITERIA

INCLUSION CRITERIA:

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

EXCLUSION CRITERIA:

i. Subjects with any condition which in the opinion of the investigator makes the subject unsuitable for inclusion.
ii. Subject has an elevated resting heart rate (>100 bpm) or blood pressure (SBP ≥140 or DBP ≥90 mm Hg).
iii. 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.
iv. Subject has a history of orthopaedic injury or surgery within the last year.
v. Known hypersensitivity to herbal drugs/nutritional supplement/ foods
vi. Subjects who is consuming/ has received any performance enhancing therapy during last 2 months
vii. Subjects undergoing any weight loss or diet plan during the trial period
viii. Chronic alcoholics
ix. Drug abusers
x. Participation in any other clinical trial during last 30 days
xi. Simultaneous participation in another clinical trial.

SAFETY PROFILE:

Safety data was collected during trial period and included recording of spontaneously reported and directly observed adverse events, vital signs and changes in laboratory test values for standard haematology and biochemistry variables throughout the trial period.

The clinical safety was evaluated by recordings of vital signs and any spontaneously reported and all directly observed adverse events.

The clinical variables to be measured for safety were the following vital signs:

- Systolic and diastolic blood pressure - mmHg
- Heart rate - beats/minute
- Respiratory rate per minute
- Body temperature - °C

TESTOFEN® had been very well tolerated by all subjects in 8 weeks. Only one dropout was reported from TESTOFEN® group whereas Placebo reported 4 dropouts. All the vital parameters, Blood Biochemistry, Kidney Function, Liver Function and Immune Function found to be all right during the study period.

Table 1: Vital parameters of the subjects enrolled in the study [Mean].

PARAMETER	TESTOFEN® (n=29)	Placebo (n=26)	'p' t-test
Heart Rate [beats per min.]	76.21	75.62	0.268
Respiratory Rate [per min.]	17.17	17.31	0.519
Systolic Bld. Press. [mm Hg]	113.10	115.00	0.360
Diastolic Bld. Press. [mm Hg]	73.10	75.23	0.297
Body Temperature [^{0}F]	97.93	97.77	0.140

Both TESTOFEN® and Placebo group are homogenous groups. All the vital parameters are in conformity with the inclusion criteria.

Table 2: Safety Profile details

PARAMETER		TESTOFEN® (n=29)	Placebo (n=26)
Random BSL	Pre-Treatment	87.66	90.27
	Post-Treatment	86.86	88.92
	'p' paired t-test	0.691	0.568
SGOT	Pre-Treatment	25.00	23.96
	Post-Treatment	23.72	23.00
	'p' paired t-test	0.459	0.278
SGPT	Pre-Treatment	32.93	30.04
	Post-Treatment	30.83	28.12
	'p' paired t-test	0.284	0.152
Alkaline Phos.	Pre-Treatment	75.72	75.31
	Post-Treatment	78.45	80.73
	'p' paired t-test	0.489	0.030
Bilirubin (Total)	Pre-Treatment	0.95	0.90
	Post-Treatment	0.91	0.88
	'p' paired t-test	0.148	0.609

Bilirubin (Direct)	Pre-Treatment	0.40	0.38
	Post-Treatment	0.36	0.33
	'p' paired t-test	0.085	0.061
Bilirubin (Indirect)	Pre-Treatment	0.56	0.53
	Post-Treatment	0.55	0.56
	'p' paired t-test	0.831	0.187
Creatinine	Pre-Treatment	1.14	1.06
	Post-Treatment	0.94	0.97
	'p' paired t-test	<0.0001	0.053
BUN	Pre-Treatment	28.28	26.42
	Post-Treatment	25.62	26.62
	'p' paired t-test	0.0001	0.845

Table 3: Blood Biochemistry

PARAMETER		TESTOFEN® (n=29)	Placebo (n=26)	'p' t-test
Hemoglobin	Pre-Treatment	13.36	13.46	0.718
	Post-Treatment	13.51	13.67	0.557
	'p' paired t-test	0.271	0.262	-
Hematocrit	Pre-Treatment	40.52	40.58	0.942
	Post-Treatment	40.79	41.19	0.743
	'p' paired t-test	0.495	0.171	-
MCV	Pre-Treatment	90.50	90.10	0.546
	Post-Treatment	88.70	90.97	0.326
	'p' paired t-test	0.400	0.196	-
MCHC	Pre-Treatment	32.97	33.16	0.250
	Post-Treatment	33.12	33.22	0.579
	'p' paired t-test	0.337	0.776	-
RBC Count	Pre-Treatment	4.48	4.51	0.765

	Post-Treatment	4.49	4.53	0.682
	'p' paired t-test	0.824	0.742	-

All blood biochemistry parameters have remained within acceptable physiological limits.

Table 4: Blood Immune Profile

PARAMETER		TESTOFEN® (n=29)	Placebo (n=26)	'p' t-test
	Pre-Treatment	9706.90	8903.85	0.011
	Post-Treatment	8562.07	8376.92	0.626
WBC Count	'p' paired t-test	0.002	0.138	-
	Pre-Treatment	2.34	2.62	0.698
	Post-Treatment	1.76	1.54	0.480
Eosinophils	'p' paired t-test	0.239	0.034	-
	Pre-Treatment	0.00	0.00	1.000
	Post-Treatment	0.00	0.00	1.000
Basophils	'p' paired t-test	-	-	-
	Pre-Treatment	63.45	59.19	0.009
	Post-Treatment	61.45	63.50	0.093
Neutrophils	'p' paired t-test	0.131	0.003	-
	Pre-Treatment	33.28	37.58	0.012
	Post-Treatment	35.66	33.96	0.140
Lymphocytes	'p' paired t-test	0.100	0.013	-
	Pre-Treatment	0.83	0.62	0.269
	Post-Treatment	1.14	1.00	0.566
Monocytes	'p' paired t-test	0.107	0.086	-
	Pre-Treatment	257586.21	255461.54	0.880
	Post-Treatment	260068.97	259846.15	0.986
Platelets	'p' paired t-test	0.872	0.718	-

There had been some changes with respect to immunological parameters, which go in sync with the earlier reported studies in which impairment of immune function due to intense exercise is been reported.

EFFICACY:

Primary efficacy was assessed on the basis of following parameters;

I. Anabolic Activity by Nitrogen Absorption measured by BUN
II. Blood Testosterone both Total and Free.
III. Total Lymphocyte count and check immunity.

Secondary efficacy will be assessed on the basis of following parameters;

1. Exercise Physiology Biomarkers
- Serum Creatinine
- Serum Prolactin

2. Body Composition
- Change in Fat-Free Mass
- Change in Percent Body Fat
- Change in Fat Mass
- Change in Body Weight

3. Muscle size
- Change in thigh: maximal girth, inferior to the gluteal fold.
- Change in flexed arm: maximal girth at mid upper arm; elbow flexed and muscle contracted.
- Change in shoulders: across the maximal protrusion of the deltoids.
- Change in chest: mid-tidal volume.

DATA ANALYSIS:

Parametric methods were used to compare treatment groups on change from baseline measurements. Statistical methods employed to carry out such comparisons was modified, as required, to accommodate any baseline differences between groups should they occur, or to otherwise reduce the error variance associated with the models.

RESULTS:

PRIMARY EFFICACY PARAMETERS

1. BUN: Blood Urea Nitrogen in Serum as a measure of Nitrogen uptake and Retention:

Parameters	**(Mean Value)**		
	TESTOFEN®	**PLACEBO**	
Pre Treatment	28.28	26.62	
Post Treatment	25.62	26.42	
P value	0.0001	0.845	
Percentage change with respect to Baseline.	- 7.92	1.36	P Value < 0.05

BUN has demonstrated a significant decrease with respect to base line in TESTOFEN® ($p < 0.0001$). Whereas, it has shown an increase in Placebo. Blood urea nitrogen can be a measure of nitrogen uptake in muscles signifying anabolic activity. Decrease in BUN signifies a significant anabolic activity. TESTOFEN® group has a significant decrease in BUN compared to increase in Placebo ($p < 0.05$).

2. Free Testosterone pg/ml. Physiological Limits (Male – 8.69 to 54.69 pg/ml):

PARAMETERS	TESTOFEN®	PLACEBO	
Pre Treatment	17.76	21.30	
Post Treatment	35.29	37.70	
P value	0.0001	0.014	
Percentage change	96	48 *	P Value < 0.05

* Sports Medicine Vol.26, Number 2, August 1998, pp 101-117, Kargotich, Goodman Univ: west Australia. "The influence of exercise induced plasma volume changes on the interpretation of Biochemical Parameters".

Although there is increase in both groups TESTOFEN® group increase is double of Placebo. After adjusting for plasma changes it is significant. ($p < 0.05$). Thus TESTOFEN® group has shown significant increase with respect to base line ($p < 0.0001$) and with respect to placebo ($p < 0.05$).

3. Lymphocytes:

PARAMETERS	TESTOFEN®	PLACEBO	
Pre Treatment	33.28	37.58	
Post Treatment	35.66	33.96	
P value	0.100	0.014	
Percentage change	11.21	- 7.29	P Value < 0.003

TESTOFEN® has shown increase in Lymphocytes with respect to base line. Placebo has shown significant decrease with respect to base line ($p < 0.02$). This is in line with previously published data. Intense and chronic exercise leads to impairment of immunity. If we look at the percentage change, TESTOFEN® has a significant increase in Lymphocytes with respect to Placebo ($p < 0.03$)

SECONDARY EFFICACY PARAMETERS

1. **Creatinine:** Serum creatinine indicates the level of degradation of creatine from muscle tissues in normal subjects having good kidney function.

PARAMETERS	TESTOFEN®	Placebo	
Pre Treatment	1.14	1.06	
Post Treatment	0.94	0.97	
P value	0.0001	0.053	
Percentage change	- 16.66	- 4.99	P Value < 0.02

Serum creatinine has decreased significantly both in TESTOFEN® and Placebo group signifying that Creatine uptake and recycle in muscle are increased by exercise. However, TESTOFEN® group showed a percentage decrease of 16.66 compared to Placebo of 4.99 ($p < 0.02$). This confirms that TESTOFEN®

exerts a beneficial effect on Creatine uptake and recycle in muscle cells over and above physical workout.

2. **Prolactin (ng/ml). Physiological Limits Men 2.1 to 17.7 ng/ml:**

PARAMETERS	TESTOFEN®	Placebo	
Pre Treatment	6.44	9.11	
Post Treatment	10.95	10.90	
P value	0.0001	0.093	
Percentage change	70	19.60	P value < 0.04

Prolactin increase in exercise is predicted due to stress. As a result both TESTOFEN® and Placebo have shown significant increase with respect to base line. However, TESTOFEN® has shown significant percentage increase compared to Placebo ($p < 0.04$). This increase can be attributed to:

a. Increased Prolactin secretion from Leucocytes

b. Increased Prolactin secretion from metabolised (Estradiol) of increased free Testosterone

3. **BODY COMPOSITIONS**

PARAMETERS	TESTOFEN®	Placebo
TRICEPS		
Pre Treatment	7.48	7.85
Post Treatment	5.97	7.20
P value	0.003	0.280
THIGH		
Pre Treatment	9.83	10.62
Post Treatment	8.39	9.57
P value	0.003	0.098
CHEST		
Pre Treatment	4.86	5.08
Post Treatment	3.33	3.21
P value	0.003	0.006

Skin fold thickness in Triceps, Thigh and Chest have significant reduction with respect to baseline. However Placebo has also shown significant decrease in Chest but not in Triceps and Thigh. Percentage changes are not statistically significant.

4. MUSCLE SIZE

PARAMETERS	TESTOFEN®	Placebo
THIGH		
Pre Treatment	54.41	53.12
Post Treatment	54.33	51.73
P value	0.943	0.001
FLEXED ARM		
Pre Treatment	34.31	33.02
Post Treatment	34.57	33.56
P value	0.324	0.09
SHOULDER		
Pre Treatment	44.91	42.77
Post Treatment	41.88	41.27
P value	0.006	0.03
CHEST		
Pre Treatment	93.62	91.58
Post Treatment	94.00	91.56
P value	0.659	0.976

TESTOFEN® has maintained the weight and shown skin fold thickness reduction. In the light of this, if the muscle size is examined, TESTOFEN® has maintained Muscle size with exception of shoulder. Shoulder decrease could be attributed to reduction in fat.
Placebo group has increased in weight and has shown reduction in muscle of Thigh and Shoulder. Hence the readings are insignificant.

CONCLUSION:

1. TESTOFEN® group has demonstrated significant anabolic activity as evidenced by BUN reduction ($p<0.05$) compared to placebo.
2. TESTOFEN® group has significant increase in Free Testosterone ($p<0.05$) compared to Placebo.
3. TESTOFEN® group has not only compensated the loss of Immunity significantly compared to Placebo ($p<0.003$), but has also increased immunity.
4. TESTOFEN® group has shown significant reduction in Serum Creatinine levels ($p<0.02$) compared to placebo signifying Creatine uptake and recycle in muscle cell.
5. TESTOFEN® group has shown significant increase in Prolactin compared to Placebo ($p<0.04$). However this increase is within Physiological limits for men.
6. TESTOFEN® has shown significant decrease in body fat compared to baseline.
7. TESTOFEN® has maintained Muscle size despite maintaining weight and reducing fat.