Title of the study: A phase IV, 16 weeks, Multicenter, Randomized, Double-Blind, Placebo-Controlled Clinical Trial to assess the efficacy and safety of oral Tribulus terrestris (Tribestan®) in men with erectile dysfunction (mild to moderate) and/or secondary hypoactive sexual desire (low libido)

Study protocol No: TRIB – 01 – 08 EudraCT No: 2008-001998-15

Phase: IV

Study period: 9 September 2010- 29 March 2013

Study design: a multicenter, randomized, double-blind, placebo controlled

Study centres: 10 centres in Bulgaria randomized patients in this study

Number of patients: screened: 218; randomized: 180; dropped: 8; finished: 172

Treatment duration: 12 weeks

Indication: Erectile dysfunction; secondary hypoactive sexual desire (low libido)

Medication: Patients meeting pre-defined inclusion and exclusion criteria were randomly assigned to receive Tribestan (Tribulus terrestris) 250 mg film-coated tablets 3x2 tablets daily after meals or Placebo 250 mg film-coated tablets 3x2 tablets daily after meals for 12 weeks treatment period

Objectives: Primary: to compare the efficacy and safety of Tribestan vs Placebo on erectile function and sexual desire in men with erectile dysfunction and low libido; to monitor the safety profile of Tribestan.
Secondary: to evaluate the effect of Tribestan on the level of Total cholesterol, LDL, HDL, triglycerides

Endpoints: The primary endpoint was the change of erectile function score, evaluated by IIEF after 12 weeks treatment period with Tribestan film-coated tablets after meal. IIEF is a standardized questionnaire for evaluation of erectile function with score ranges from 0 to 30 (1-5 and 15 question).
The secondary endpoints were:
•Overall estimation of sexual function by IIEF;
•Adverse Events monitoring;
•Laboratory measurements(hormones);
•Lipids profile;
•Blood pressure

Statistical methods: ANOVA model with baseline measurement as covariate as principal method for statistical inferences and in addition, Student's two independent samples t-test as secondary method. The conclusions were based on the former. LS Means were used to conclude the superiority. The final decision had based on 95% confidence interval of difference.

Study population

	Tribestan	Placebo
Number of patients, n	90	90
Age (yrs.), mean ± SD	44.11 ±12.37	41.18 ± 12.36
Height (m), mean ± SD	1.77 ± 0.06	1.77 ± 0.08
Weight (kg), mean ± SD	85.91 ± 16.15	87.83 ± 16.66
BMI (kg/m2), mean ± SD	27.47 ± 4.65	28.04 ± 4.49
Duration of ED (months), means ± SD	13.73± 13.43	16.37 ± 15.72
Moderate ED, n (%)	27 (15.00)	29 (16.11)
Mild ED, n (%)	63 (35.00)	61 (33.89)
Diabetes mellitus, n (%)	3 (10.71)	6 (21.43)
Hypertension, n (%)	8 (28.57)	7 (25.00)
Other concomitant diseases, n (%)	3 (10.71)	1 (3.57)

Primary Results:

	Tribestan, n=90	Placebo, n=90
IIEF score at Baseline (mean (SD))	18.01 (3.21)	18.22 (3.44)

IIEF score after 12 weeks (mean (SD))	22.76 (5.11)	20.19 (4.73)
LS Mean Difference	2.70	
95% CI	1.40-4.01	
p-value	<0.000068	
Secondary results: There is a significant difference between Tribestan and Placebo over all visits- Intercourse Satisfaction (p=0.0005), Orgasmic Function (p=0.0325), Sexual Desire (p=0.0038), Overall Satisfaction (p=0.0028) There is not a significant difference in lipid levels between the two groups after the treatment - p-values are greater than fixed level of 5%. Total testosterone, free testosterone, DHEA-S, and SHBG do not differ for two treatment arms (p-values are greater than level of significance fixed at 5%). The blood pressure remains nearly uninfluenced over time.		
Safety results:		
	Tribestan N=90	Placebo N=90
SAE		
Bronchopneumonia	0	1
AE		
Abdominal pain	1	0
Gastroesophageal reflux	0	1
Conclusion: The differences in outcomes between the two groups clearly established that Tribestan is superior to Placebo in improving the erectile function and sexual desire in men with mild to moderate ED and/or low libido after 12 weeks treatment. Both Tribestan and Placebo are equally well tolerated without any signs of clinically significant adverse effects on physical findings and in laboratory parameters.		
Publication: No publication		