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Tribulus Treats Menopausal Syndrome Symptoms

Where to Buy Tribulus

This study reports that "The opinion of the research team, based on the experience from treatment of more than 150 women with natural or postoperative menopause, is that Tribulus can successfully be used for treatment of the menopausal syndrome in women."

Clinical Studies on Tribulus terrestris Protodioscin in Women with Endocrine Infertility or Menopausal Syndrome

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Summary: The opinion of the research team, based on the experience from treatment of more than 150 women with natural or postoperative menopause, is that Tribulus can successfully be used for treatment of the menopausal syndrome in women. Tribulus treatment resulted in the complete or almost complete disappearance of all or most of the menopausal syndrome symptoms were found in 49 from 50 treated patients (98%). The study also noted that Tribulus restores and improves libido sexualis in men, improves and prolongs the duration of erection, and also that Tribulus exerts a stimulating influence on spermatogenesis by increasing the number of spermatozoa and their mobility. It increases the level of testosterone.

The therapeutic effect of Tribulus terrestris' protodioscin on the endocrine function of women was studied by the team in the last few years. The first clinical trials were carried out on women with the dysovulatory syndrome and infertility and later they were redirected to the premenopausal and menopausal syndrome. Women with postoperative castration-induced menopause were included in a separate group.

Materials and methods
The Tribulus terrestris extract in the form of 250 mg film tablet containing the superterrestrial part of the plant with a predominant content of protodioscin. Control experiments were performed with placebo tablets of the same commercial appearance.

Regimens of application
Group A – women with dysovulatory disorders and infertility.

- Regimen recommended by the producer: 1-2 tablets 3 times daily for a period of 2 to 3 months.
- Our regimen 3x1 tablets up to 3x2 tablets daily from the 5th to the 14th day of the menstruation cycle for a total

period of 2-3 months.
- After follow-up of a set of parameters to evaluate the integral effect of the Tribulus preparation only the regimen is switched over to combined therapy with Tribulus and hormonal preparation to stimulate ovulation:

1. Tribulus according to the second regimen and Stimobul (Organon) 1-2 tablets from the 5th to the 14th day of the cycle for 3 months total.
2. Tribulus according to the second regimen and Clostylbegit (Hungary) 1-2 tablets daily from the 5th to 9th day of the cycle for 3 months.

Group B – women with menopausal syndrome.
- Tribulus at 3x2 tablets for 20 days and tapering the dosage by 1 tablet every 4-5 days to come down to the maintenance dose of 2x1 tablets per day for a total period of time strictly individualized depending on the degree of the effect obtained.
- Tribulus at 2x2 tablets for 30 days with subsequent reduction in the dosage every 4-5 days to 2x1 tablets daily.
- Tribulus at 3x1 tablets continuously for a long period of time (up to 1 year).

Clinical contingent
Group A – 51 women with diagnosed primary and secondary endocrine infertility treated in the First Gynecological Hospital “T. Kirkova”, Sofia, from 1984 to 1984. Fifteen of these women were treated by the first regimen and 36 by the second regimen After a 3-month period of observation, the combined therapy of the third regimen was used on 20 of these women. Parallel control studies on a comparable contingent were carried out with hormone preparations: Stimovul (Organon) on 62 women; Clostylbegit (Hungary) on 21 women, Fertodur (Schering) on 29 women. The total number of women covered by the study was 163.

Group B – 50 women with diagnosed natural or post-castration menopausal syndrome treated in the period 1986 to 1987. A pilot study with 12 more women was carried out in 1984. In 46 of 50 women (92%), immediately after verifying the diagnosis and the degree of manifestation of the clinical picture of menopause, we initiated treatment with placebo of 3x2 tablets daily for a total period of 15 to 30 days. After having registered the effect of placebo, we continue with the Tribulus therapy using the above regimens.

Parameter of observation and recording

For the clinical contingent of Group A
The final result from the treatment was classified in 3 types: normalization of ovulation with subsequent pregnancy, normalized ovulation without pregnancy; and no effect. The following parameters were recorded: subjective sensations (changes) in general conditions and libido sexualis; onset and duration of menstruation; basal temperature; hormonal vaginal cytopreparations; pregnandiol, 17-KC and 17-OH-KC in the urine histological changes in the endometrium; echographic folliculometry; radio immunological control of gonadotropic and steroid production; hysterosalpingographs and laparoxopy to determine the state of the fallopian tubes and their elimination, as far as possible as causes of infertility.

For the clinical contingent of Group B
The results of treatment were classified depending on the clinical picture as complete disappearance of menopausal complaints; great decrease of the former; and no effect on complaints.

The following parameters in the nervous vegetative and neuro-psychic complaints intensity and frequency of the hot flashes and sweating, depression or superexcitation, easy fatigueability, apathy, etc.; changes in the cardiovascular system including changes in pulse and blood pressure, oppression in the heart region, tachycardia or extrasystoles, etc.; micturition disorders, pruritus in the external genitalia; hormonal cytopreparations; blood count and blood sugar profile; ultrasonic diagnostics; radioimmunological control of gonadotropic and steroid hormones; as well as libido sexualis.

Results and discussion

Group A
Fifteen patients were treated by the first regimen, none of them showed any essential changes in parameters determining the occurrence of ovulation. Moreover, there were noted some undesirable effects such as a longer menstruation cycle, excessive libido sexualis, related general excitability, insomnia, and in case of abrupt discontinuation of the drug intake at the end of the third month or even in reducing the dose by 50% only – a dramatic decrease of libido sexualis and general weakness. It made necessary to apply the second regimen to the

remaining 36 patients – the date are down in the following figures and tables. The distribution of women treated with Tribulus is given on Figure 1. The prevailing number of them were in the age group 28 to 30 years old and only 2 were over 36 years of age. Nineteen patients were with primary hormonal infertility and 18 with secondary hormonal infertility, i.e. the number was almost equal, see Figure 2. The distribution of patients with regard to previous treatment is shown on Figure 3. One can note that those untreated previously were about 36% of the women: others with prior hormonal or surgical correction of ovaries were of almost the same number – 20 to 30% and the smallest was the group with combined hormonal and surgical therapy. In Table 1 we show lower values of unsatisfactory treatment with Tribulus (33.3%) compared to Clostylbegit (52.4%) or Fertodur (76%). Undoubtedly best results were obtained with Stimovul normalized ovulation with subsequent pregnancy of 39%, normalized ovulation without resultant pregnancy of 35.5% and no effect of 26%. Tribulus has a considerably more moderate effect: 24 of the total number of 36 treated women had normalized ovulation but only in 2 of them was followed by pregnancy and in 12 patients it had no basic effect. Twenty women were treated simultaneously with Tribulus and an ovulation stimulant. The effect from their combined use was better compared to treatment with single agents. Probably here there is a complex effect – hormonal stimulation of ovulation is combined with increased libido sexualis and improved general and psyche-emotional condition of the infertile couple particulary taking into account the fact that we recommend the use of Tribulus also to the husbands. No side effects were observed in the intermittent application of Tribulus.

Age distribution of female patients treated with protodioscin
Figure 1

Age distribution of female patients treated with protodioscin
Figure 2

Distribution of female patients treated with protodioscin by preceding hormonal, surgical, or combined therapy
Figure 3

Comparative data on the effect of Tribulus, Stimovul, Clostybegit, Fertodur on females with endogenous infertility
Table 1

Group by method of treatment	**Number**	**Therapeutic results**			
		Normalized ovulation with pregnancy	*Normalized Ovulation no pregnancy*	*No effect*	*Side effects*
Treated with Tribulus terrestris	36	2 (5.6%)	22 (61.1%)	12 (33.3%)	-
Treated with Stimovul	62	24 (38.7%)	22 (35.5%)	16 (85.8%)	4 (6.5%)
Treated with Clostylbegit	21	4 (19.0%)	6 (28.6%)	11 (52.4%)	8 (38.1%)
Treated with Fertodur	29	2 (6.9%)	5 (17.2%)	22 (75.9%)	3 (10.6%)
Total	*148*	*32*	*55*	*61*	*15*

Group B

The age distribution of the patients in this group is represented on Table 1. Only four of them are younger than 40 years and 2 over 60 years of age. Eighty percent of all treated women are in the age group 40 to 55.

Twenty six patients were with the natural onset of menopause and the remaining 24 (48%) – postoperative castration climacteric (Table 2). The duration of the menopausal syndrome is shown on Table 3. As seen in a considerable part of patients the menopause dated back on the year prior to therapy with Tribulus. Those were mainly women with postoperative menopause.

Distribution of patients by age
Table 1

Age Group (yrs)	**Number of patients**	**Percent**
30-34	1	2.0
35-39	3	6.0
40-44	8	16.0
45-49	19	38.0
50-54	13	26.0
55-59	4	8.0
60	2	4.0
Total	*50*	*100.0*

Effect of Tribulus during menopause distribution of patients by type of menopause
Table 2

Type of menopause	Number of patients	Percent
Natural	26	52.0
Postoperative	24	48.0
Total	*50*	*100.0*

Distribution of patients by duration of menopause
Table 3

Duration of menopause (months)	Number of patients	Percent
< 12	19	38.0
12 - 35	16	32.0
36 - 60	7	14.0
> 60	8	16.0
Total	*50*	*100.0*

The clinical picture of the menopausal syndrome in the group under study was predominated by several major symptoms represented diagrammatically on Tables 4 and 5.

Effect of protodioscin during menopause distribution of patients by incidence of some symptoms before treatement
Table4

Symptoms	Number of patients	Percent
Hot flashes	50	100
Perspiration	39	78
Depression	27	54
Hyperexcitation	22	44
Sleeplessness	41	82
Tenseness	18	36
Feeling of heaviness	30	60
RR-changes	11	22
ECG-changes	8	16

Distribution of patients by type of libido sexualis
Table 5

Type of libido sexualis	Number of patients	Percent
Normal	2	4.0
Low	20	40.0
Very low	28	56.0
Total	50	100.0

Nervous vegetative manifestations were quite frequent with all treated women. The hot flash was present in 100% of women, sweating in 78%, insomnia in 82%, and unmotivated superexcitation in 44%.

From the cardiovascular changes, the heaviness in the heart region was predominant (60%) and changes in the blood pressure and ECG were observed in 16 women (22%). Libido sexualis was unchanged in only two women (in comparison with the previous state) greatly decreased to completely lost desire for sexual contacts were characteristic to 56% of all patients.

It should be noted that the intake of placebo tablets by 46 from 50 women did not result in a favorable effect on any complaint (Table 6)

Distribution of patients by duration of placebo treatment
Table 6

Duration of treatment (days)	Number of patients	Percent
0	4	8.0
14	6	12.0
15 - 20	32	64.0
21 - 30	8	16.0
Total	*50*	*100.0*

According to the selected signs for classification we established, complete or almost complete disappearance of all or most of the symptoms were found in 49 from 50 treated patients (98%). Only in one woman did Tribulus not have an effect on the menopausal syndrome and she was transferred to other treatments. Table 7 shows that in 50% of the treated women the course of treatment needed not less than 110 up to 180 tablets to achieve favorable effect. In 10% of the women this dose was even higher – 190 to 220 tablets. The average effective doses are given in Table 8 and in the greater number of women those were more than 100 tablets per course of treatment. The effect obtained was retained by a maintenance dose of 2 to 3 tablets a day in 84% of the treated women (Table 9).

Distribution of patients by the total effective dose of protodioscin
Table 7

Total number of tablets	**Initial dose (tablets / day)**							
	3x1		**2x2**		**3x2**		**Total**	
	No.	**%**	**No.**	**%**	**No.**	**%**	**No**	**%**
< 60	2	4	-	-	-	-	2	4
60 - 100	5	10	5	10	8	16	18	36
110 - 180	-	-	7	14	18	36	25	50
190 - 220	-	-	1	2	1	2	2	4
> 220	-	-	-	-	3	6	3	6
Total	*7*	*14*	*13*	*26*	*30*	*60*	*50*	*100*

Total effective dose of protodioscin
Table 8

Dose (tablets/day)	**Number**	**Total effective dose**
		Mean Limit of confidence (mean+1.96 SEM)
3 x 1	7	68.6 53.0 - 84.2
2 x 2	13	115.4 93.7 - 137.1
3 x 2	30	141.5 113.7 - 169.3

Distribution of patients by the supporting dose of protodioscin
Table9

Supporting dose (tablets/day)	**Number of patients**	**Percent**
2 x 1	27	55.1
3 x 1	14	28.6
2 x 2	8	16.3
Total	*49**	*100.0*

*1 patient without effect

The dynamic cytological monitoring of the progesterone – estrogen level (vaginal cytopreparation) showed that only in 14% of the patients there was present a high initial level of estrogen, while in 44% of them it was low or very low (Table 10).

Distribution of patients by level of progesterone/estrogen according to hormonal cytological examination
Table 10

Level	**Number of patients**	**Percent**
High	7	14
Normal	1	2
Low	6	12
Very low	16	32
Total	30*	100

* 20 patients without cytological examination

The particularly strict radioimmunological monitoring is shown on Table 11 and Table 12.

Effect of protodioscin during menopause radioimmunoassays
Table 11

Hormone	**Protodioscin treatment**	**Number**	**Limit of confidence (mean + 1.96 SEM)**
FSH	Before	46	51.38 + 72.34
	After	42	42.30 + 59.74

LH	Before	42	32.45 + 46.05
	After	43	29.62 + 38.28
Prl	Before	42	265.20 + 378.20
	After	37	200.60 + 267.60
E2	Before	43	0.2 + 0.22
	After	40	0.2 + 0.54
Prg	Before	32	5.0 + 10.3
	After	34	4.14 + 7.44
Tst	Before	41	1.15 + 1.74
	After	45	0.96 + 1.30

The variance analysis showed that both the mean values and the confidence interval are within the limits normal to the age. Comparison of these data prior to and after therapy showed that gonadotropic hormones levels decreased compared to the initial values, while the ovarian hormones did not demonstrate such a decrease. There was even an insignificant increase especially in the E2 hormone. These data together with the clinical picture can account for the favorable influence on the menopausal complaints and the considerably enhanced libido sexualis in two-third of the treated women.

In this case the effect of Tribulus is equivalent, and in some cases even better than, that of the estrogen-testosterone hormonal preparation Ambosex without the adverse side effect of the latter such as virilization and tendency for weight gain.

Side effect in treatment with Tribulus
Nausea, vomiting, allergy phenomena, and intolerance were not observed. The preparation is well tolerated. It is worthwhile to note the fact that after achieving the desireable effect the abrupt decrease in the effective dose down to the maintenance dosage results in the sudden and complete unlocking of almost the whole menopausal symptom complex. Therefore, the transition from the effective dose to the maintenance dose should be gradual and for a longer period of time.

Conclusion
Our long-term experience with the use of the preparation Tribulus for treatment of infertility mainly in women, but quite frequently in men as well, make us recommend it for disturbed gamete formation due to stress situations, long years of infertile marital life, impaired or almost missing libido sexualis, leading to anovulatory menstruation cycles, dyskinetic changes of fallopian tubes and qualitative changes in the sperm.

A combination of Tribulus with suitable hormone preparations results in potentiating its positive effect which explains its use in everyday practice for treatment of infertility in the family.

The opinion of the research team, based on the experience from treatment of more than 150 women with natural or postoperative menopause, is that Tribulus can successfully be used for treatment of the menopausal syndrome in women.

Tribulus
Composition: Tribulus is a natural product, obtained from the overground part of the plant Tribulus terrestris, containing mainly saponins of the furostanol type with a predominant quantity of protodioscin (no less than 45%).

Action: non-hormonal preparation which restores and improves libido sexualis in men, improves and prolongs the duration of erection. It exerts a stimulating influence on spermatogenesis by increasing the number of spermatozoa and their mobility. It increases the level of testosterone.

It improves libido sexualis in women, exerts a slight stimulating ovulation effect, it has a favorable influence on vasomotory manifestation during natural and post-castration climacterium, as well as on subjective complains such as insomnia, general tenseness, irritability or apathy, etc.

Indication: in men – impotentia coeundi in Klinefelter's syndrome, varicocele, Cryptorchism, hypotrophy of testicles, syndrome of Noonan, sterility on the basis of idiopathic oligoasthenozoospermia idiopathic azoospermia, varicocele.

In women – endocrinous ovarian sterility, climacteric and post-castration syndrome with expressed vasomotory and neurasthenic manifestations.

Contraindication – none

Application: in men – the dosage and duration of treatment are determined according to the character and gravity of disease. Most often, the dose is 1 to 2 tablets 3 times a day during meals. The treatment duration is as follows: in case of impotential coeundi: 40 to 50 days at least in sterility 70 to 90 days.

In women, the treatment is strictly individual and depends on the gravity of manifestations. The dose most often used here is also 1-2 tablets 3 times a day during meals. In cases of sterility the preparation is applied from the first to the twelveth days of the menstruation cycle. In postcastration and climacteric syndrome the treatment lasts 60 to 90 days. After an improvement is obtained the dose is reduced to 2 tablets daily for another 50 to 60 days as supporting dose.

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