CLINICAL STUDIES

Genopause®

A blend of ayurvedic plants for women health

Role of the Ayurvedic formulation GENOPAUSE on neuro-psycho-physiological assessments among menopausal women

THE CLINICAL

Up to date, two clinical studies have been carried out with **Genopause®**, the first one was carried out on 2003 (not published) and the second on 2016 (under peer-review).

FIRST CLINICAL STUDY

156 women aged 40-60 years, having evidenced 1 complete year of cessation of menstrual cycle, were recruited to participate in a 6-months double blind randomized placebo-control study to evaluate the efficacy of **Genopause®** in menopausal symptoms.

Participants were selected from the gynecology outpatient department S.S. Hospital of Varanasi city and were divided in to two groups:

- Group I: 70 menopausal women receiving placebo
- Group II: 86 menopausal women receiving 1 g Genopause® (2 x 500 mg/daily)

Kupperman Index was adopted to determine the improvement of menopausal symptoms as deducted by the global score of Kupperman Index (KI). Vasomotor symptoms i.e. the hot flushes was assessed separately as it is the most important presenting symptoms among menopausal cases. The evaluation was made at the months 0, 3 and 6 from the beginning.

After 6 months of treatment, the frequency of hot flushes was significant reduced (Table 1).

Groups	Nº cases	Vasomotor symptoms (hot flashes)		
		Initial	Month 3	Month 6
Group I (placebo)	70	7.09 ± 4.32	7.77 ± 2.80	6.29 ± 3.09
Group II (treated)	86	6.28 ± 3.45	5.47 ± 2.07 †	2.91 ± 2.49 *†

* p < 0.001 comparison initial vs. second follow up
† p < 0.001 comparison between groups

Table 1.
Effect of test formulation on vasomotor symptoms among menopausal women.

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The complaint of paresthesia made by menopausal women also improved after six months of **Genopause®** treatment. The changes in **Genopause®** group were statistically significant when compared to the initial values (p<0.001). Placebo treatment did not exert any significant difference (Table 2).

Groups	Nº cases	Paresthesia		
		Initial	Month 3	Month 6
Group I (placebo)	70	3.54 ± 1.81	3.71 ± 0.92	2.97 ± 1.51
Group II (treated)	86	3.70 ± 1.83	2.95 ± 1.09 †	0.95 ± 1.09 *†

* p < 0.001 comparison initial vs. second follow up
† p < 0.001 comparison between groups

Table 2.
Effect of test formulation on paresthesia (Kuperman Index) among menopausal women.

Other parameters and situations that were improved with **Genopause®** treatment, included a reduction in the severity of sleep disturbances as well as a better management of nervousness situations. Some menopausal women presented headache as major clinical symptoms that was only significant reduced in **Genopause®** group.

Concerning lipid profile the Ayurvedic formulation had a good effect on regulating the total cholesterol including different fractions of the cholesterol and also corrected triglycerides and HDL-C ratio which has been considered as one of the most important factors in the onset on cardiovascular disease.

SECOND CLINICAL STUDY

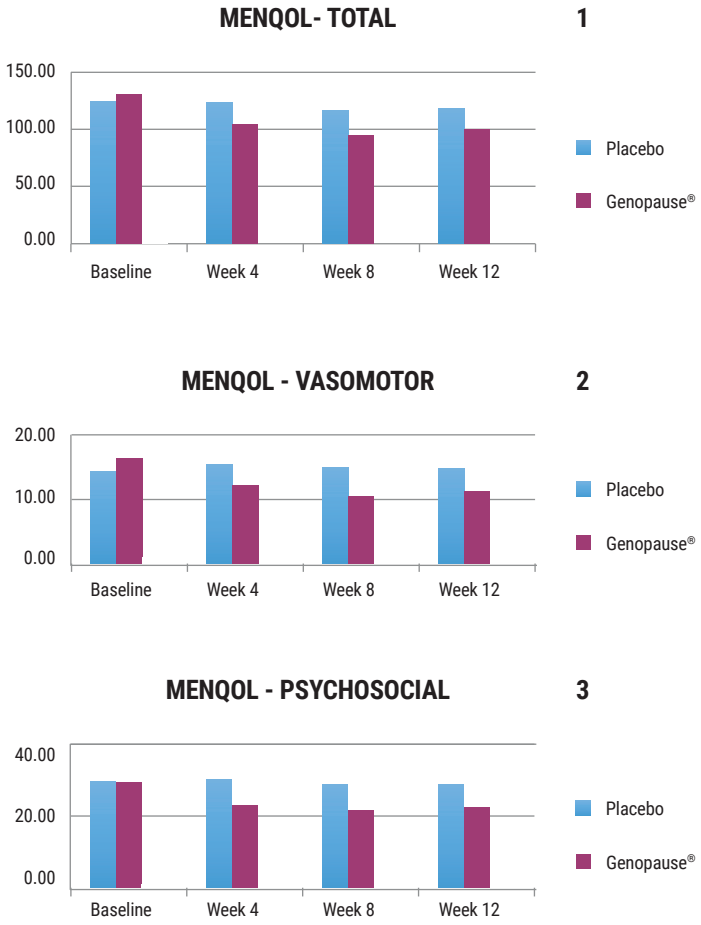
The study was held on March 2016 by the Australia Sydney University, School of Medicine (Brisbane). The study population included healthy women, experiencing symptoms of menopause, aged 40 to 65 years, recruited through the CRO's subject database and public media. After the screening, 97 women experiencing menopausal symptoms were recruited to participate in a 12-weeks double blind randomized placebo-control study to evaluate the efficacy of **Genopause®** in menopausal symptoms.

Women were divided in to two groups:

- Group I: 47 menopausal women receiving placebo
- Group II: 50 menopausal women receiving 1 g of **Genopause®** (2 x 500 mg/daily)

The primary outcome measure was the efficacy of treatment for menopausal symptoms using the Menopause-Specific Quality of Life Questionnaire (MENQOL). Participants were asked to record a 7-day diary of hot flushes and night sweats prior to commencing the trial and at week 4, week 8 and week 12 (Figures 1-5).

Figures 1-5. Average reduction in MENQOL total and domain scores for Active treatment group and Placebo group at Baseline, week 4, week 8 and week 12.



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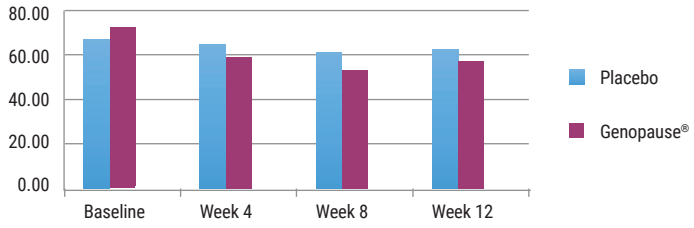
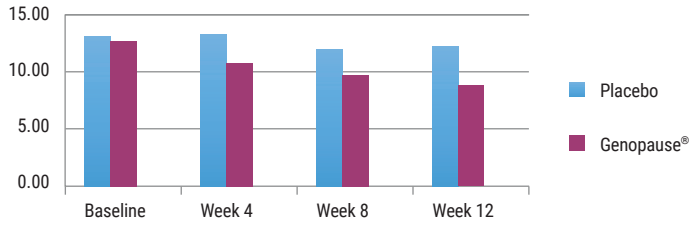
MENQOL - PHYSICAL 4



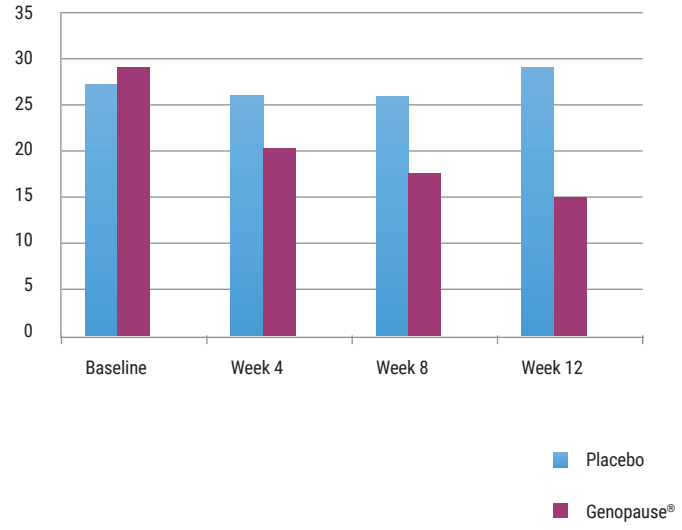
MENQOL - SEXUAL 5



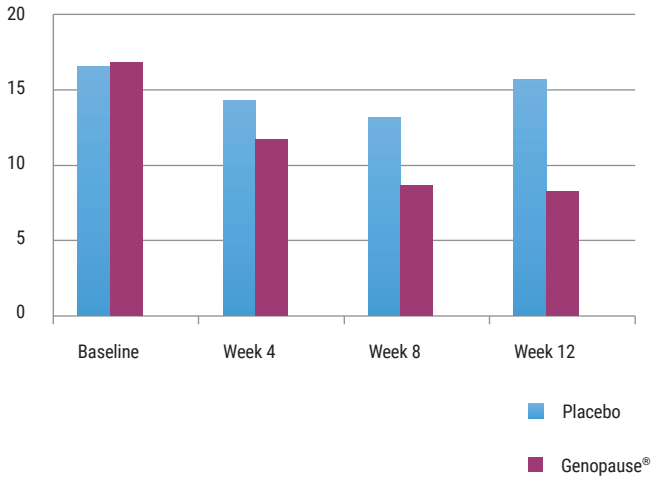
The patient-report 7-day diary of Hot Flushes and Night Sweats showed a gradual reduction in total flushes in the active treatment group, reducing to 70% in the first 4 weeks, to 67% by 8 weeks and a further slight reduction to 51% by week 12 (Figures 6-8).

Figures 6-8. Average reduction in Total Flushes, Day-time Flushes and Night Sweats for Active treatment group and Placebo group at Baseline, week 4, week 8 and week 12.

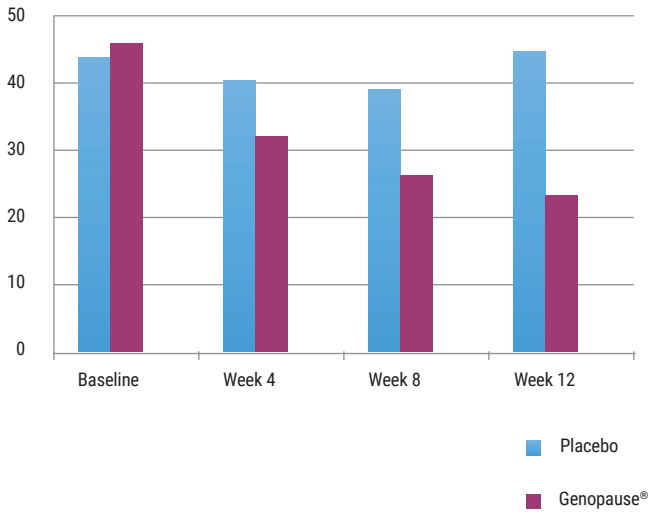
DAY-TIME HOT FLUSHES 6



NIGHT SWEATS 7



TOTAL DAY-TIME FLUSHES & NIGHT SWEATS 8



GENOPAUSE®: CONCLUSIONS

The two clinical studies unambiguously demonstrated that the decline in psychological capabilities that occurs as result of the normal aging process is arrested by the combination of Ayurvedic plants that may be used in the management of cognitive impairment, psychic involvements including other physiological disturbances associated with menopausal women.

In summary, the Ayurvedic composition of **Genopause®** was directly responsible of its efficacy. In this sense, *Asparagus recemosus* offers protection against a variety of biological, physical and chemi-

cal stressors. Due to this property, the vasomotor symptoms including other psychological and psychiatric symptoms are improved in menopausal women.

Tinospora cordiofolia that has been included in the present test formulation has been found beneficial in several studies. The anti-inflammatory, analgesic, hepatoprotective and antistress properties of this plant has been proven in several studies. It shows changes in norepinephrine, dopamine, 5-hydroxytryptamine and 5-hydroxyindoleacetic acid levels.

It has been proven that whitanolides contained in *Whitania somnifera* acts on brain producing tranquility and decreasing excitatory neurotransmisors. This is the reason that by improving nervousness, insomnia, anxiety depression including mental performance the general health of the post-menopausal women also improved.

Commiphora mukul is one of the ingredients of the present test formulation, which has been found to be a highly potent anti-inflammatory agent. In addition, guggulipid has significant hypolipidemic activity. Thus, the regulation of dyslipidemia reduced the risk of occurrence of coronary heart disease among the menopausal women as the estrogen deficiency is the most important causative factor of hyper cholesterolemia and dyslipidemia.

The osteoarthritic changes are also the important presenting clinical symptom of menopausal women. Reduction in bone mass, dyslipidemia, generalized atrophy of connective tissues can directly be affected by estrogen deficiency. *Conmiphora mukul* is also useful for the treatment of osteoarthritis particularly of Knee joint. In the present series of investigations, menopausal women reported improvement in movement that were restricted due to osteoporosis.

It has been summarized that the present herbal formulation improves the psychophysiological deterioration by correcting various clinical symptoms including anxiety and depression among the menopausal women. The test formulation has definite role in the regulation of dyslipidemia and thus prevents the atherosclerosis.

The management of vasomotor complaint (hot flush) and osteoporosis following test drug treatment indicated the reduced possibly of bone fractures and vasoconstriction or coronary attack causality among the menopausal women.

None of the cases showed any adverse reaction during entire course of study.

A mild modification in systolic and diastolic blood pressure was noticed in following test drug treatment when the average initial systolic blood pressure was compared with the values of after six months in treated group the difference are not significant while in case of diastolic blood pressure changes are significant. On the contrary, there was a gradual rise in the levels in placebo treated group.

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