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Research Communication

EVALUATION OF CLINICAL EFFICACY AND SAFETY OF ZANOPAUSE TABLET AN HERBAL FORMULATION IN PRE-MENOPAUSAL AND MENOPAUSAL WOMEN

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Abstract:
Background: *To evaluate the clinical efficacy and safety effect of Zanopause tablet a marketed herbal formulation of Emami Ltd., in pre-menopausal and menopausal women*
Methods: *50 women patients age range between 40 to 70 years old suffering from pre-menopausal and menopausal symptoms like hot flashes, night sweats, irregular periods, loss of libido, vaginal dryness and mood swings. Zanopause tablet was given twice a day for 60 days.*
Results: *A significant improvement was observed in clinical symptoms like hot flashes, night sweats, irregularity of periods, loss of libido, vaginal dryness and mood swings after ZZT medication. Laboratory investigation showed improved Haemotological levels in all the patients. Other parameters were observed in normal range. On '0th' day 7.6 - 14.1 (G %), 8.1 – 14.7 (G %) on 45th day and 8.7 – 15.2 (G %) on 60th day. ZZT medication showed a significant increase in Haemoglobin level of patients. 5200 - 9900 (/ cu.mm.) on '0th' day, 5600 - 1100 (/ cu.mm.) on 45th day and 4.01-5800 - 9700 (/ cu.mm.) on 60th day, WBC count was observed in normal range, from the data obtained from blood samples of 50 patients. Upper Abdomen USG was normal in all the 50 patients.*
Conclusion: *Menopause symptoms like hot flashes, night sweats, irregularity of periods, loss of libido, vaginal dryness were taken care off. Increase in Haemoglobin levels and status of wellbeing. Reduce pain in knee joints were observed.*

Keywords: *Zanopause tablet, Pre-menopausal and Menopausal symptoms*

Background

All healthy women transition from a reproductive, or premenopausal, period, marked by regular ovulation and cyclic menstrual bleeding, to a postmenopausal period, marked by amenorrhea. The onset of the menopausal transition is marked by changes in the menstrual cycle and in the duration or amount of menstrualflow.[1] subsequently, cycles are missed, but the pattern is often erratic early in the menopausal transition. Menopause is defined retrospectively after 12 months of amenorrhea.

As the menopause transition progresses, hormone levels are variable, but estrogen levels fall markedly and levels of follicle-stimulating hormone increase. After menopause, ovulation does not occur. The ovaries do not produce estradiol or progesterone but continue to produce testosterone. A small amount of estrogen is produced by the metabolism of adrenal steroids to estradiol in peripheral fat tissue.

Once women's are post-menopausal, they may regain energy, but also be at higher risk for certain conditions. Medication and/or healthy lifestyle changes may reduce the risk of some of the conditions associated with menopause. Follicle Stimulating Hormone (FSH) is a hormone produced by the pituitary gland (located at the base of the brain). FSH levels will dramatically rise as ovaries begin to shut down; these levels are easily checked through blood test which leads to confirmation of menopause. Postmenopausal women should undergo regular check-ups and

preventive screening tests such as pelvic exams, pap smears, breast exams, and mammograms are among the most important things.[2]

According to Ayurveda, menstruation (raja-pravrutti) is the natural flow of excess pitta in the form of menses (raja). Raja-nivrutti is the state of gradually diminished raja-pravrutti which ends as menopause. Menopausal age coincides with the woman's transition from the pitta time period of her life in to the vaata time period. Many of the symptoms that are experienced with menopause are a combination of the three doshas - vaata, pitta and kapha. A woman's hormones are governed by pitta and kapha. Ayurveda looks upon menopause as an imbalance of pitta and vaata doshas. These two doshas accumulate, spread and localize in the vital metabolic tissues manifesting as symptoms and consequences of menopause. This is one reason why many women will experience hot flushes (pitta) and weight gain (kapha) when they are menopausal. Nervousness and affected sleep will be part of vaata imbalance.3

Menopausal symptoms affect about 70% of women approaching menopause. Typical menopause symptoms, such as hot flushes or night sweats, are caused by changing hormonal levels in the female reproductive system. Almost all women notice early symptoms while still having periods. This stage of gradually falling and fluctuating hormone levels is called pre-menopause, which often begins in the early 40s.

The symptoms of menopause usually last for the whole menopause transition (until the mid-50s), but some women may experience them for the rest of their lives. The most common symptoms are: hot flushes, night sweats, irregular periods, loss of libido and vaginal dryness.4,5

A pink coloured smooth, round, biconvex film-coated tablet, weighing 550 mg was prepared using extracts of Glycine max seed (Soya-100 mg), Seed of Trigonella foenum-graecum (Methi-75 mg), Stem bark of Terminalia Arjuna (Arjuna-75 mg), Rhizomes of Valeriana wallichi (Tagar-50 mg) and Zinc oxide (Yasad bhasma-25 mg) along with excipients, a polyherbal tablet, developed by Emami Ltd., Kolkata.

For the present study, this herbal formulation has been selected to establish the efficacy and safety of Zandu Zanopause Tablet (ZZT) on Ayurvedic & modern subjective and objective clinical parameters. Clinical parameters on menopausal symptoms like hot flashes, night sweats, irregular periods, loss of libido, and vaginal dryness were evaluated.

Methods

Sample Size: 50 patients completed study (Total Enrolled: 57 i.e. 7 patient dropout during study)
Trial period: 02 months for each patient
Design of the study: Open Observational Trial.
Drug & dosage: Zanopause tablet twice a day after food with a glass of Luke warm water (approx. 250 ml.) maintaining 12 hours gap in between, for 2 months (60 days).
Follow - Up: The follow-up was carried out after 15 days of treatment.
Duration of the study: 60 days drug therapy with a follow up for 15 days without drug.
Study period: 08 months.
Study Site: Mahavir Hospital, Latti Plot, Opp. District Library, Near C. J. Hospital, Surendranagar - 363001, Gujarat, India.

Subject Inclusion Criteria:
Enrollment: Patients found eligible were judged by the inclusion & exclusion criteria. Patients were formally informed about the study.

Informed consent: A written informed consent was obtained from all the patients, indicating purpose and nature of clinical trial-herbal formulation. The procedures to be carried out and the potential risks and benefits were explained to the study patients in detail in non-technical terms. They were assured that they can withdraw from the study at any time without explaining their

action Medication and treatment: The patients were treated with Zanopause tablet, 1 tablet, twice daily and the treatment period was 2 months. The medicine was kept in secured storage in the office of the principle investigator and was allotted to the patients following a random number table.

Criteria for Exclusion:

Patients who develop secondary complication of Colitis, intestinal obstruction or any other serious illness e.g. Hepatic/ renal failure. Patient with diagnosed other than arthritis like Gallbladder stone, Hepatomagely. Patient receiving any other method of treatment.

Parameters for evaluation:

Clinical efficiency parameters: all patients enrolled into the study were subjected to thorough history taking and clinical examination and also questionnaire as part of the screening procedure. They were re-evaluated at the end of the study (clinical research form). Apart from clinical examination and questionnaire, the selected investigations were done, before and after medication. Each subject visited the clinic at least 5 times during the study.

Safety information:

Any serious adverse event was not expected but the clinical research form had the provision for recording any serious adverse event if it happened and the principle investigator of the trial would report the sponsor same on urgent basis.

Concomitant medication:

Subject were advised not to use any concomitant medication unless absolutely necessary. If any concomitant medication was used, its record was maintained in a separate section of the clinical research form.

Confidentiality:

All procedures in the study were carried out maintaining strict confidentiality. Patient identity, medical condition and trail data was not disclosed to or discussed with any third party. Criteria regarding Menopausal symptoms were: Hot Flashes, Night Sweats, Irregular Periods, Loss of Libido, Vaginal Dryness and Mood Swings

Routine Examination and Assessment:

The full details of history and physical examination of the patients was recorded as per the Performa (Forms I & II). Clinical assessment was done and recorded on '0' day (before ZZT medication), 15th day, 30th day, 45th day and 60th day. Regularity or irregularity of menstrual cycle or menopause period along with menopausal symptoms like hot flashes, night sweats, irregular periods, loss of libido, vaginal dryness and mood swings was noted. Grading score of symptoms was done as per its severity observed in an individual patient (like occasionally = 0, mild = 2, moderate = 4, sever = 6). All of these parameters were observed during the period of ZZT medication. Haematological Parameters were performed on '0', 45th day and 60th day including total WBC and haemoglobin content, differential leukocyte count for polymorphs, lymphocytes, eosinophils, monocytes and basophils.

Routine and Microscopic Urine Examination was performed on '0', 45th day and 60th day including physical parameters like quantity, colour, odour, deposits and clarity; Chemical parameters like albumin, sugar, bile salts and bile pigments and Microscopical parameters like pus cells, RBC, WBC, epithelial cells, casts, crystals, yeast cells, T. vaginalis and bacterial parameters.. Upper Abdomen USG study was performed on '0th' day and 60th day.

Result and Discussion

Improvements were observed in clinical, haematological and urine examination of ZZT medicated 50 women patients age range between 40 to 70 years old.

Body Mass Index:

The BMI is generally used as a means of correlation between groups related by general mass as tabulated in Table 1; it can serve as a vague means of estimating adiposity.

Table 1:
BMI

Patient Code	BMI	Patient Code	BMI	Patient Code	BMI	Patient Code	BMI	Patient Code	BMI
ZZT-1	26.45	ZZT-11	22.95	ZZT-21	27.42	ZZT-31	26.34	ZZT-41	27.42
ZZT-2	39.71	ZZT-12	20.75	ZZT-22	25.18	ZZT-32	29.9	ZZT-42	25.18
ZZT-3	30.89	ZZT-13	22.21	ZZT-23	26.57	ZZT-33	24.8	ZZT-43	26.57
ZZT-4	39.41	ZZT-14	30.57	ZZT-24	18.2	ZZT-34	20.08	ZZT-44	22.21
ZZT-5	27.03	ZZT-15	22.21	ZZT-25	26.28	ZZT-35	20	ZZT-45	24.41
ZZT-6	28.77	ZZT-16	17.19	ZZT-26	21.24	ZZT-36	27.83	ZZT-46	28.1
ZZT-7	25.55	ZZT-17	23.49	ZZT-27	22.27	ZZT-37	21.58	ZZT-47	18.77
ZZT-8	24.39	ZZT-18	27.76	ZZT-28	24.79	ZZT-38	28.93	ZZT-48	19.53
ZZT-9	28.62	ZZT-19	27.03	ZZT-29	23.65	ZZT-39	20.62	ZZT-49	18.6
ZZT-10	25.2	ZZT-20	18.02	ZZT-30	28.39	ZZT-40	26.72	ZZT-50	24.48

Religion and Diet:

Most of patients are of Hindu religion, vegetarian in diet as shown in Table 2 and 3 respectively.

Table 2:
Patient based on Religion

Religion	Number of Subject
Hindu	45
Muslim	3
Christian	2
Others	0

Table 3:
Patient based on Diet

Diet	Number of Subject
Veg	45
Non-Veg	0
Lecto-Veg	5

Menstrual Cycle Pattern:

41 patients were suffering from menopausal symptoms and 9 patients were having irregular periods, Table 4.

Table 4:
Patient based on Menstrual Cycle

Total Patients	Menopausal	Irregular Period	Regular
50	41	9	0

Haematological Data:

Laboratory investigation showed improved Haemotological levels in all the patients. Other parameters were observed in normal range. Haematological improvement data of 50 patients within 60 days is shown in Table No. 5. ZZT medication showed a significant increase in Haemoglobin (G%) at 0th day, 45th day and 60th day as shown in Table 6 and Figure 1. WBC (/cu. mm.) at 0th day, 45th day and 60th day is shown inTable 7 and Figure 2.

Table 5:
Haematological improvement data of 50 patients within 60 days

Days of treatments	Hb (G %) range	WBC (/cu. mm.) range
0 days	7.6 - 14.1	5200 - 9900
45 Days	8.1 – 14.7	5600 - 1100
60 days	8.7 – 15.2	5800 - 9700

Table 6:
ZZT data for Hb (G %)

Haemoglobin (G%) at 0th day, 45th day and 60th day																			
Patient Code	0th day	45th day	60th day	Patient Code	0th day	45th day	60th day	Patient Code	0th day	45th day	60th day	Patient Code	0th day	45th day	60th day	Patient Code	0th day	45th day	60th day
ZZT-1	10.4	11.5	12	ZZT-11	9.9	10.5	11.2	ZZT-21	8.2	8.8	9.4	ZZT-31	9.1	9.6	10.2	ZZT-41	10.5	11.1	12
ZZT-2	8.9	9.3	10.4	ZZT-12	11	11.8	12.4	ZZT-22	8.4	9.1	9.7	ZZT-32	12.5	13.1	13.6	ZZT-42	9.2	9.8	10.4
ZZT-3	11.1	11.6	12.1	ZZT-13	9.3	10	10.7	ZZT-23	7.6	8.2	8.8	ZZT-33	11.7	12.3	12.7	ZZT-43	10.1	10.7	11.5
ZZT-4	9.8	10	10.6	ZZT-14	11.6	12.1	12.8	ZZT-24	9.4	10.2	10.8	ZZT-34	9.1	9.6	10.2	ZZT-44	10.3	10.9	11.7
ZZT-5	10.8	11.2	11.9	ZZT-15	9.4	10.2	10.8	ZZT-25	8.6	9.4	9.6	ZZT-35	7.6	8.1	8.7	ZZT-45	10.2	10.8	11.5
ZZT-6	7.6	8.1	8.7	ZZT-16	12.2	12.8	13.2	ZZT-26	10.4	11	11.5	ZZT-36	8.5	9.1	9.6	ZZT-46	10.1	10.6	11.6
ZZT-7	11	11.7	12.3	ZZT-17	10.3	11.1	11.7	ZZT-27	10.2	10.8	11.3	ZZT-37	7.8	8.2	8.8	ZZT-47	9.2	9.8	10.7
ZZT-8	11.4	12.1	12.1	ZZT-18	8.5	9	9.6	ZZT-28	9.9	10.5	11.1	ZZT-38	9.5	10.1	10.7	ZZT-48	12	12.5	13.1
ZZT-9	13.3	13.9	14.9	ZZT-19	8.7	9.2	9.6	ZZT-29	9.2	9.8	10.4	ZZT-39	10.6	11.1	11.7	ZZT-49	10.1	10.7	11.6
ZZT-10	8.6	9.2	9.9	ZZT-20	9.4	10.1	10.6	ZZT-30	14.1	14.7	15.2	ZZT-40	8.7	9.1	9.6	ZZT-50	13.1	13.6	14.1

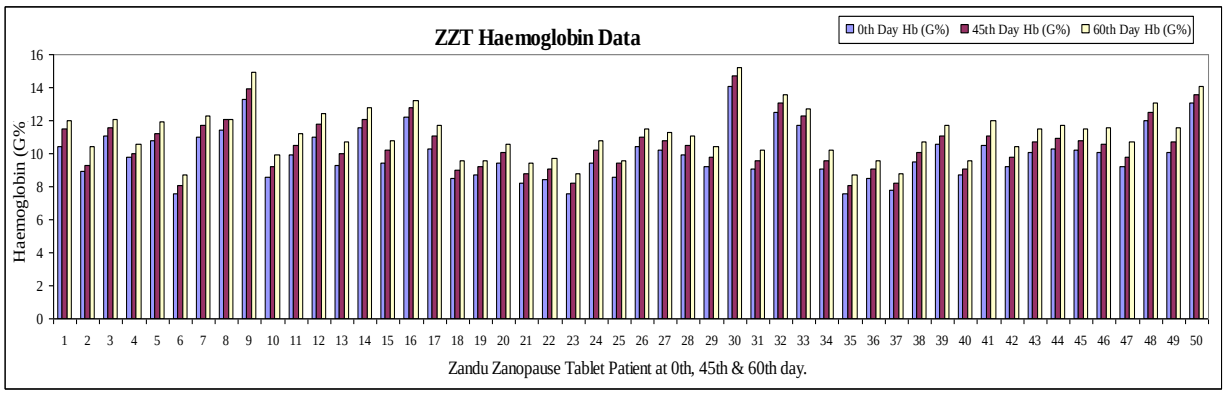


Figure 1: ZZT Haemoglobin (G %) at 0th day, 45th day and 60th day

Table 7:
ZZT data for WBC

WBC (/cu. mm.)																			
Patient Code	0th day	45th day	60th day	Patient Code	0th day	45th day	60th day	Patient Code	0th day	45th day	60th day	Patient Code	0th day	45th day	60th day	Patient Code	0th day	45th day	60th day
ZZT-1	5200	7300	8200	ZZT-11	8700	7500	7400	ZZT-21	7500	7800	7100	ZZT-31	6900	7800	7500	ZZT-41	8700	8100	7900
ZZT-2	7800	6500	7400	ZZT-12	8400	8500	8900	ZZT-22	8900	8300	7200	ZZT-32	6300	6000	6600	ZZT-42	8100	7800	7500
ZZT-3	9800	9400	8500	ZZT-13	6500	7100	8400	ZZT-23	9200	8100	7300	ZZT-33	8900	8200	8600	ZZT-43	9200	8800	8400
ZZT-4	7800	5600	5800	ZZT-14	8900	7900	7400	ZZT-24	9700	8200	7400	ZZT-34	9900	7800	7900	ZZT-44	8900	8600	7900
ZZT-5	9700	10100	9700	ZZT-15	7400	8200	7100	ZZT-25	8400	8400	7500	ZZT-35	9600	7600	8000	ZZT-45	9600	8900	8400
ZZT-6	5200	6500	7500	ZZT-16	9200	11100	9700	ZZT-26	8900	8600	7600	ZZT-36	8900	8800	8100	ZZT-46	8400	7900	7400
ZZT-7	9800	8900	7800	ZZT-17	5400	6300	7400	ZZT-27	7900	7900	7700	ZZT-37	8800	8200	6900	ZZT-47	8900	8400	7800
ZZT-8	7100	6000	7500	ZZT-18	7800	8100	8500	ZZT-28	9100	8200	7800	ZZT-38	9100	8500	6900	ZZT-48	7500	7200	6800
ZZT-9	8400	8100	8700	ZZT-19	5200	6500	7400	ZZT-29	8900	8100	7800	ZZT-39	9600	7800	7200	ZZT-49	8200	7500	6800
ZZT-10	8400	8100	7200	ZZT-20	7500	7300	8100	ZZT-30	8200	8700	8600	ZZT-40	7900	8700	7600	ZZT-50	7800	7300	6900

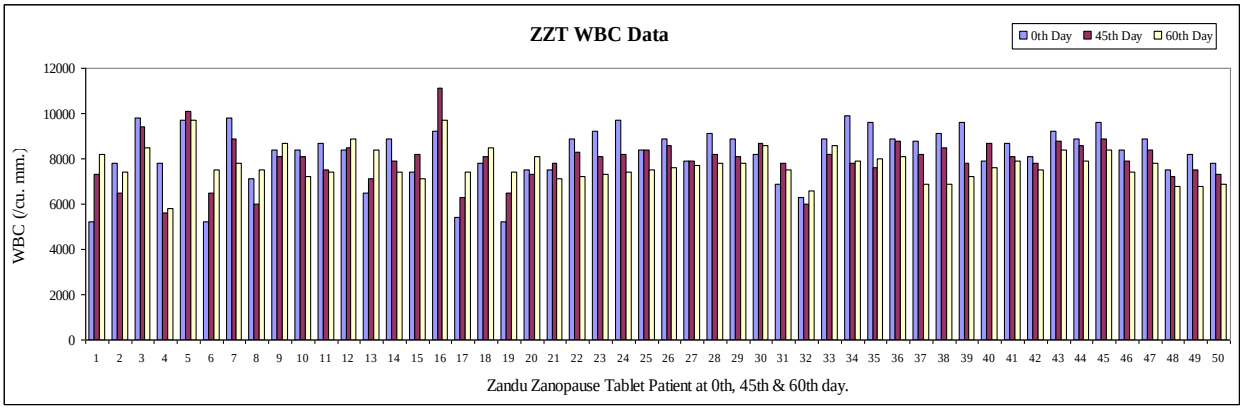


Figure 2: ZZT WBC (/cu. mm.) at 0th day, 45th day and 60th day

Statistical Analysis of Clinical Parameters:

Clinical assessment was done (symptoms score Occasionally = 0 Score, Mild = 2 Score; Moderate = 4 Score and Sever = 6; as per the Clinical trial format) and recorded on the zero day (i.e. one day before administering the trial drug), 15th day, 30th day, 45th day and on the final day of the follow-up (i.e. on 60th day) as per the severity of symptoms.

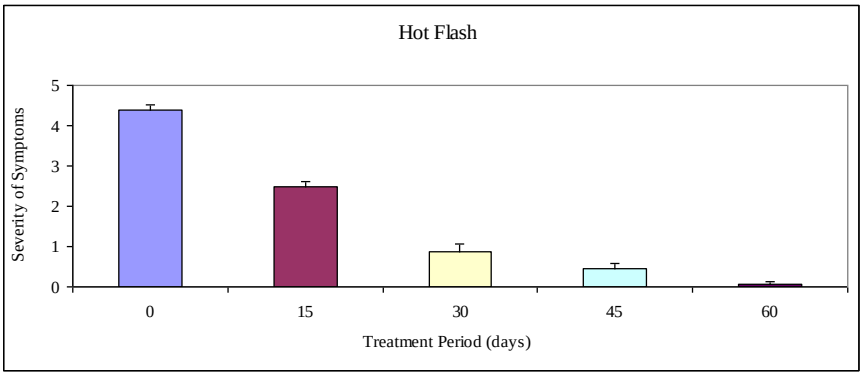
As the score of menopausal symptoms were reduced towards the end of the trial (60 days), it revealed a significant activity of the Zanopause tablet formulation, as shown in Table 8. Graphical data of hot flashes, night sweats, irregularity of periods, loss of libido, vaginal dryness and mood swings (severity of symptoms) versus treatment period for Zanopause tablet of Figure 3 - 8 Results were reported by mean ± S.E.M., the test of significance was statistically analysed by using one way ANOVA test, followed by Dunnett's multiple comparison test ($p < 0.01$). Statistical analysis was done by using software Graph pad Prism Demo version 3.

Table 8:
Treatment of Menopausal Symptoms, Zanopause tablet

Days	Hot Flash	Night Sweats	Irregular Periods	Loss of Libido	Vaginal Dryness	Mood Swings
0th	4.4 ± 0.1143	4.24 ± 0.1323	4	3.9535 ± 0.1689	4 ± 0.1789	4.6383 ± 0.1457
15th	2.48 ± 0.1464**	2.36 ± 0.1478 **	2.2222 ± 0.0943 **	2.1395 ± 0.1434 **	2.3043 ± 0.1786 **	2.7234 ± 0.1607 **
30th	0.88 ± 0.1821**	0.92 ± 0.1734 **	1.7778 ± 0.17 **	0.9767 ± 0.1558 **	1.4783 ± 0.1513 **	1.8723 ± 0.1493 **
45th	0.44 ± 0.1314**	0.36 ± 0.1238 **	0.6667 ± 0.1414 **	0.6047 ± 0.1314 **	0.7826 ± 0.1396 **	1.2766 ± 0.1374 **
60th	0.08 ± 0.0560**	0.04 ± 0.04 **	0.2222 ± 0.0943 **	0.0930 ± 0.0603 **	0.1739 ± 0.0806 **	0.5106 ± 0.1247 **

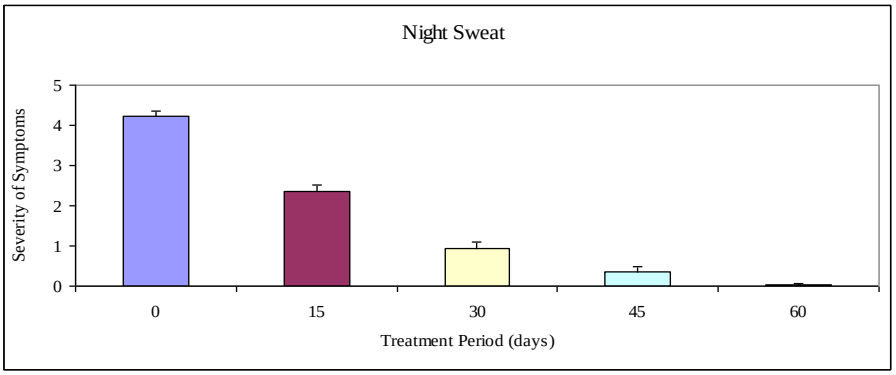
All values are in Mean ± S.E.M., ** p<0.01 = More significant vs. Control (0th day untreated patients); n = 50

Figure 3: Graph of Hot Flash, Severity of Symptoms versus treatment period for Zanopause tablet.



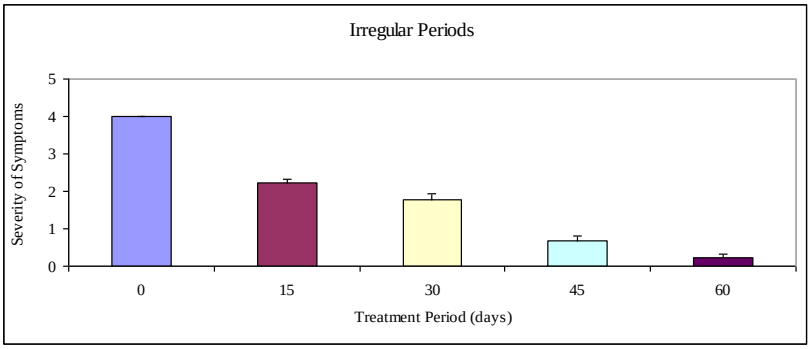
All values are in Mean ± S.E.M., ** p<0.01 = More significant vs. Control (0th day untreated patients); n = 50

Figure 4: Graph of Night Sweat, Severity of Symptoms versus treatment period for Zanopause tablet.



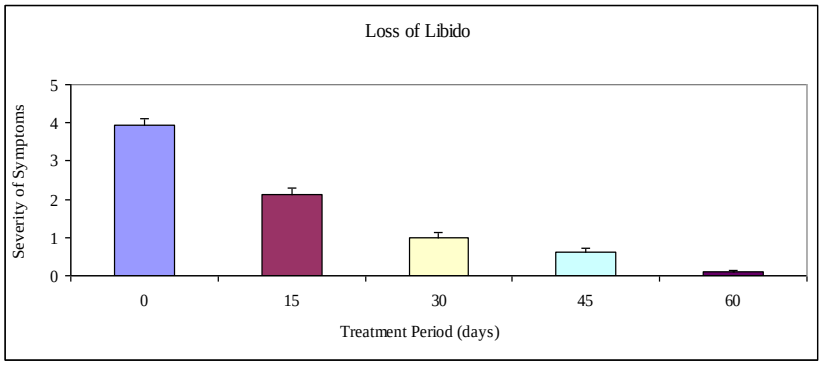
All values are in Mean ± S.E.M., ** p<0.01 = More significant vs. Control (0th day untreated patients); n = 50

Figure 5: Graph of Irregular Periods, Severity of Symptoms versus treatment period for Zanopause tablet.



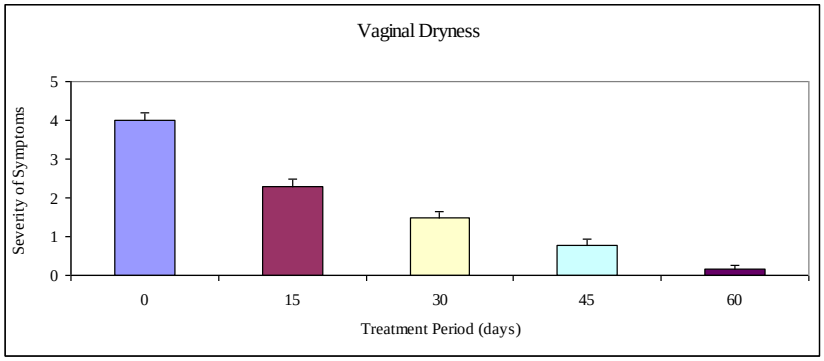
All values are in Mean ± S.E.M., ** p<0.01 = More significant vs. Control (0th day untreated patients); n = 50

Figure 6: Graph of Loss of Libido, Severity of Symptoms versus treatment period for Zanopause tablet.



All values are in Mean ± S.E.M., ** p<0.01 = More significant vs. Control (0th day untreated patients); n = 50

Figure 7: Graph of Vaginal Dryness, Severity of Symptoms versus treatment period for Zanopause tablet.



All values are in Mean ± S.E.M., ** p<0.01 = More significant vs. Control (0th day untreated patients); n = 50

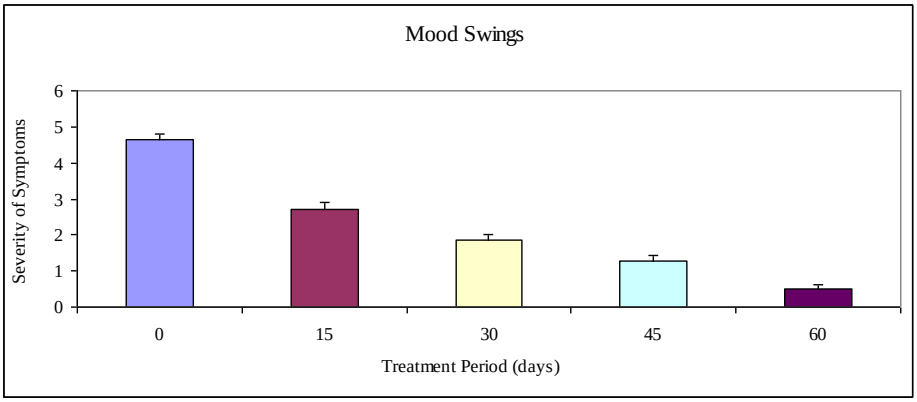


Figure 8: Graph of Mood Swings, Severity of Symptoms versus treatment period for Zanopause tablet.

All values are in Mean ± S.E.M., ** $p<0.01$ = More significant vs. Control (0^{th} day untreated patients); n = 50

As per the study design, total 57 patients were incorporated out of which 50 continued till the end of study. Patients were selected as per inclusion criteria and who doesn't fall in any one of the exclusion criteria. All necessary laboratory investigations were completed before starting the treatment with Zanopause tablet. The patients selected had complaint of inadequate clinical symptoms like hot flashes, night sweats, irregularity of periods, loss of libido, vaginal dryness and mood swings along with that some was having poor well-being.

0^{th} Day Visit:

All the patients were given the samples of test medicine, Zanopause tablet. Patients were informed about the dose, effect of the drug and were advised to have follow up every 15 days, upto two months and if any harmful or unwanted or unexplained effect was noted and the drug should be stopped immediately and to inform as soon as possible. A complete general, systemic, laboratory and upper abdominal USG examination of each patient was carried out in detail, to note any change in further visits.

15^{th} Day Visit:

All the patients were examined in detail after 15 days of starting the treatment. It was observed that subject was having no major changes in hot flashes, night sweats, and irregularity of periods, loss of libido, vaginal dryness and mood swings. It was observed that no any major change in either of pulse, B.P., respiration etc. The systemic examination also was not altered at all. There was no any harmful effect noted either to patient.

30^{th} Day Visit:

After 15 days they were further called for the consultation. Each patient was examined in detail for their hot flashes, night sweats, irregularity of periods, loss of libido, vaginal dryness and mood swings symptoms. No any significant harmful effect noted with the use of the product. The responses regarding the improvement in symptoms for patient were satisfactory at least.

45^{th} Day Visit:

At the end of 45^{th} day they were further called for the consultation. Each subject was examined in detail for their clinical and laboratory investigation of blood and urine sample. Hot flashes, night sweats, irregularity of periods, loss of libido, vaginal dryness and mood swings

symptoms were showing signs of improvement. Increase in haemoglobin levels, increase in status of well-being along with reduce pain in knee joints were observed.

60th Day Visit:

In last visit, they were examined and the laboratory investigations done, the differences in pre and post treatment parameters were observed. The present study demonstrated that the pre-menopausal and menopausal symptoms like hot flashes, night sweats, irregular periods, loss of libido, vaginal dryness and mood swings were significantly reduced as compared to control (0th day untreated patients). The observations reported and the benefits noted from this product in menopausal women are discussed in detail.

Zanopause tablet is a polyherbal formulation containing extracts derived from seed of Glycine max (Soya), Seed of Trigonella foenum-graecum (Methi), Stem bark of Terminalia Arjuna (Arjuna), Rhizomes of Valeriana wallichi (Tagar) and Zinc oxide (Yasad bhasma) along with excipients.

It has been postulated that dietary intake of *Glycine max* contains Soya isoflavones that have an effect on phytoestrogens. These play an important role in steroid mechanism and synthesis, thus affecting the female hormone synthesis. Isoflavones have estrogen receptor agonism and antagonism activity. Thereby reducing the symptoms of menopause.[6,7] *Trigonella foenum-graecum* is having estrogen like activity.[8] *Terminalia arjuna* is a unique herb that helps maintain a healthy heart and reduces the effects of stress and nervousness. Arjuna promotes effective cardiac functioning, regulates blood pressure, treatment of osteoporosis and other bone related disorders as it improves the synthesis and secretion of female hormones.[9] *Valeriana wallichii* has considerable reputation for its traditional use in inflammatory conditions[10], pain[11], epilepsy, insomnia, neurosis, sciatica.[10,12] The plant is widely used in the treatment of anxiety and depression either alone or in combination with other herbs.[13-15] *Yasad bhasma* is the natural source of Zinc and it helps strengthens the bone density, which is to reduced due to hormonal imbalance. Thus it prevents osteoporosis after menopause.[16,17]

With the use of the Zanopause tablet which contains herbs, satisfactory and excellent results were observed within few days of use, in both pre and post-menopause patients. During every routine visit, general and systemic examination was almost unchanged; there were no reporting of any harmful effect to the patient.

With the pre and post investigations, all 50 patients showed significant increase in hemoglobin levels and status of well-being. Along with reduce pain in knee joints and menopausal symptoms like hot flashes, night sweats, irregularity of periods, loss of libido, vaginal dryness and mood swings with complete treatment of 2 months.

Herbal formulations have been proven to be as effective and safer alternatives to conventional drugs. The study indicates that Zanopause tablet provides an effective and safer alternative for long term management since it improves symptoms score at the same time positive changes are observed radiographically.

Conclusion

Menopause symptoms like hot flashes, night sweats, irregularity of periods, loss of libido, vaginal dryness were taken care off. Increase in Haemoglobin levels and status of well-being was noticed. Reduced pain in Knee joints was observed.

List of abbreviations

ZZT: Zandu Zanopause Tablet
Hb: Haemoglobin
RBC: Red Blood Corpuscles

WBC: White Blood Corpuscles
USG: Ultrasonography
BMI: Body Mass Index

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References

1. Soules MR: **Development of a staging system for the menopause transition: A work in progress.** *Menopause* 2005; **12**:117-20.
2. Randolph JF Jr, Sowers MF, Bondarenko IV, Harlow SD, Luborsky JL, Little RJ: **Change in estradiol and follicle-stimulating hormone across the early menopausal transition: effects of ethnicity and age.***J Clin Endocrinol Meta*b 2004; **89**:1555-61.
3. **Menopause and Ayurvedic treatment** [http://www.muralimanohar.com /Articles, %20English/Diseases%20and%20Conditions/Menopause.html.] Murali MC: **Raksha Ayurvedic Centre**.
4. Dennerstein L, Dudley EC, Hopper JL, Guthrie JR, Burger HG**: A prospective population-based study of menopausal symptoms.***Obstet Gynecol* 2000; **96**:351-358.
5. Nelson HD, Haney E, Humphrey L, Miller J, Nedrow A, Nicolaidis C, Vesco K, Walker M, Bougatsos C, Nygren P:**Management of menopause-related symptoms**. *AHRQ Evidence Report Summaries: March 2005; Rockville (MD)*. Agency for Healthcare Research and Quality (US), (AHRQ publication no. 05-E016-2)
6. Boulet MJ, Oddens BJ, Lehert P, Vemer HM, Visser A: **Climacteric and menopause in seven South-east Asian countries.***Maturitas* 1994; **19**:157–76.
7. Notelovitz M: **Estrogen replacement therapy: indications, contraindications and agent selection.***Am J Obstet Gynecol* 1989; **161(pt 2)**:1832-41.
8. Anthony CD: **Isoflavones, Phytohormones and Phytosterols.***J of Appl Cosmetol* 2006; **24**:17-33.
9. Nadkarni KM: **Indian Materia Medica.** 3rd ed. Bombay: Popular Prakashan; 1996b: 1198.
10. Nadkarni KM: **Indian Materia Medica**. 3rd ed. Bombay: Popular Prakashan; 1976: 1206-1262.
11. Vohra SB, Dandiya PC: **Herbal analgesic drugs.***Fitoterapia* 1992; **63(3)**:195-07.
12. Marder MH, Viola CWS, Fernandez JHM, Paladini AC: **6-methylapigenin and hesperidins: New Valeriana Flavonoids with activity on the CNS.***Pharmacol and Biol Behavior* 2003; **75**:537-45.
13. Panijel M: **Treatment of moderately severe anxiety states.***Therapiewoche* 1985; **35(41)**:4659-68.
14. Ron BH, Willis CV, Bone K, Morgan M: **Herbal products: active constituents, mode of action and quality control.***Nutrition Research Reviews* 2000; **13**:47-77.
15. Leathwood PD, Chauffard F: **Quantifying the effects of mild sedatives.***J of Psychological Res* 1982; **17**:115.
16. Sandstead HH, Lanier VC Jr, Shephard GH, Gillespie DD: **Zinc and wound healing. Effects of zinc deficiency and zinc supplementation.***Am J Clin Nutr* 1970; **23**:514-19.
17. Debjit B, Chiranjib, Sampath KKP: **A potential medicinal importance of zinc in human health and chronic Disease.***Int J Pharm Biomed Sci* 2010; **1(1)**:5-11.