Efficacy and Safety of *Pueraria mirifica* (Kwao Kruea Khao) for the Treatment of Vasomotor Symptoms in Perimenopausal Women : Phase II Study

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Abstract

Objectives : To evaluate the preliminary efficacy and safety of *Pueraria mirifica* in the treatment of vasomotor symptoms.

Design : Open-label study.

Setting : Hat Yai Regional Hospital, Thailand.

Subjects : Pre and postmenopausal women with vasomotor symptoms, such as hot flushes and night sweats. Other unpleasant symptoms, urogenital and psychological symptoms, were also evaluated.

Material and Method : Patients were enrolled voluntarily and randomly received 50 mg or 100mg of *Pueraria mirifica* in capsules, once daily for six months.

Results : Of the 48 enrolled patients, 11 cases were excluded for failing to complete the initial work-up. Thirty-seven cases were evaluated. 20 of 37 (54.1%) randomly received a dose of 50 mg/day of *Pueraria mirifica* (Group A), and 17 of 37 (45.9%) received 100 mg/day of *Pueraria mirifica* (Group B). The mean of the modified Greene climacteric scale decreased from 35.6 to 26.6, 17.2 and 15.1 in group A, while group B, declined from 32.6 to 21.0, 14.8 and 13.6 at 1-, 3- and 6-month respectively. The mean serum estradiol, fluctuated from the baseline of 76.6 to 55.4, 56.7, 72.5, 69.2, 114.2 and 74.5 pg/ml at 1-, 2-, 3-, 4-, 5- and 6-month respectively. Whereas the mean serum follicle-stimulating hormone (FSH)/luteinizing hormone (LH) was stable in the range of; 27.1/12.6, 28.3/12.9 and 22.5/11.4 mIU/ml at baseline, 3- and 6-month respectively.

Conclusions : *Pueraria mirifica*, containing phytoestrogens, relatively alleviated the climacteric symptoms in perimenopausal women. The transient negative profiles occurred in a small number of subjects that included anemia, and liver profiles. While there was a slight decrease in lipoproteins and an increase in hormonal profiles, *Pueraria mirifica* demonstrates great promise in the treatment of climacteric symptoms among perimenopausal women. However, optimal doses should be clinically assessed, to meet appropriate individual responses.

Key word : *Pueraria mirifica*, Vasomotor Symptoms, Perimenopausal Women, Phytoestrogen

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Menopause is a natural event, and understandably many women would prefer taking natural therapy rather than a drug, for managing their menopause symptoms, as well as preventing the long-term sequelae of estrogen deficiency[1]. There is an increasing public interest in foods and dietary supplements containing phytoestrogens (PE's) for the maintenance of health. In this respect PE's show a lot of promise.

PE's are natural compounds, with a biological activity similar to estrogen, which is comprised of isoflavones, lignans and coumestans. A traditional Asiatic phytoestrogen-rich diet is associated with a lower incidence of breast cancer and postmenopausal illness, and a lot of evidence indicates that PE's prevent bone resorption, increase bone density and reduce cholesterol. The estrogenic effects of PE's can be useful in preventing postmenopausal osteoporosis and cardiovascular disease. The findings from the current ongoing studies are all likely to contribute to determining the potential use of PE's as therapeutic agents[2-4].

For most women, menopause presents two sets of problems. First, most notice unpleasant symptoms such as hot flushes and vaginal dryness, but second, there are long-term sequelae arising from estrogen deficiency. The main long-term problems are an increased risk of bone loss and cardiovascular disease. Studies to date, would suggest that phytoestrogenic products may help around two-thirds of women to cope with menopausal symptoms, such as hot flushes, but there is little evidence that these products will help with vaginal dryness. However, at this point in time, the clinical data are inconclusive[5,6].

Pueraria candollei var. mirifica Airy Shaw & Suvatabandhu (Kwao Kruea Khao, White Kwao Kruea) is a legume in the family of Leguminosae. The Northern people of Thailand have medicinally used white Kwao Kruea, with the original belief of its being a life prolonging medicine, body nourishment and sense of well-being enhancement[7]. The traditional regimen is a pepper (ball) of medicine daily, which mixes the raw material with honey in the size of a black peppercorn.

Previously, the Institute of Thai Traditional Medicine, Thai Ministry of Public Health, and prior to this clinical trial[8], performed acute and sub-chronic toxicity studies in mice and Wistar rats. The authors' phase I study demonstrated and concluded that *Pueraria mirifica* is relatively safe and alleviated vasomotor symptoms in 8 perimenopausal women. This study is a follow-up phase II clinical trial, aimed at verifying the efficacy and safety of *Pueraria mirifica* for the treatment of vasomotor symptoms, using daily dosages of 50 mg and 100 mg, in larger populations.

MATERIAL AND METHOD

This was a simple trial conducted in Hat Yai Regional Hospital. Patients were recruited from the menopause clinic, outpatient department, beginning on July 3, 2000. The last patient completed the intended 24-week follow-up on September 22, 2001. Consenting females over 40 years old, with an intact uterus and at least one ovary, experiencing vasomotor symptoms, including one or more of the following; hot flushes, urogenital or psychological symptoms, night sweats with or without other unpleasant symptoms, were enrolled.

Exclusion criteria included, pregnancy, breast-feeding, unwillingness to avoid pregnancy for the duration of the trial, allergy to estrogens, having taken an estrogen replacement within 1 week prior to admission, unwillingness to continuously take the trial product for 6 months of the study, and those with chronic illnesses. The National Ethical Committee, and Institutional Review Board of the trial center, approved the protocol and informed consent was given by the women.

The primary end point of the study was to consider the effects of the product on vasomotor symptoms, from the point of screening; admission and follow-up visit at week 4, 8, 12, 16, 20 and 24. The climacteric scale used in this study was a modification of the Greene climacteric scale[9]. The secondary end points were hormonal assays; serum estradiol, serum follicle-stimulating hormone (FSH) and serum luteinizing hormone (LH), and lipoprotein analyses; cholesterol, very low-density lipoprotein (VLDL) + low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglycerides (TG). Safety was assessed using laboratory monitoring, including complete blood counts, serum glutamic-oxaloacetic transaminase (SGOT), serum glutamic-pyruvic transaminase (SGPT), bilirubin, alkaline phosphatase, blood urea nitrogen, creatinine, uric acid, and electocardiography. The subjects were randomized for dosages of 50 mg of *Pueraria mirifica* (group A) and 100 mg of *Pueraria mirifica* (group B) taken orally, in a single dose, at night.

Statistical analysis for mean, comparison of mean and Chi square tests were performed using EpiInfo version 6. If the exact values were less than 5, the Fisher exact test was used.

RESULTS

Up to six-months of responses were analyzed among thirty-seven cases for measurement outcomes. Among these, one case voluntarily withdrew from the study before the 1-month follow-up, due to intolerance to adverse events; palpitations, headache and insomnia. Six-month follow-ups were achieved in 18 of 37 (48.6%), whereas 20 (54.1%), 25 (67.5%), 32 (86.4%), 34 (91.8%) and 36 (97.3%) of the subjects maintained their follow-up at 5-, 4-, 3-, 2- and 1-month, respectively.

Twenty cases of 37 (54.1%) randomly received 50 mg of *Pueraria mirifica* and 17 of 37 (45.9%) received 100 mg of *Pueraria mirifica* orally. The mean age of the study subjects was 48.8 years. The standard deviation was 4.1 and the range was from 41 to 58 years old. The majority of the women, 32 in 37 (86.4%) were married, and 1 in 37 (2.7%) was single, 2 in 37 (5.4%) were divorced and 2 in 37 (5.4%) were widowed. None of them were in the habit of drinking alcohol, with only 1 in 37 (2.7%) a cigarette smoker. There was no statistical significance between the two groups.

The modified climacteric scale includes 20 indicators and are shown in Table 1. Each indicator will be weighted by the subjects; 0 = none, 1 = mild, 2 = moderate, 3 = severe. After medication, the mean of modified climacteric scale had decreased from 35.6 to 26.6, 17.2 and 15.1 of Group A, 50-mg product. While the Group B, 100-mg product had declined the scale from 32.6 to 21.0, 14.8 and 13.6 at 1-, 3- and 6-month respectively. The mean climacteric scale, of both Group A and Group B, was significant and decreased, $p < 0.01$. The distributions of significant indicators are demonstrated.

The partial compliance to the therapy among 19 of 37 subjects (51.3%), incomplete six months of follow-up, is distributed in Table 2. Before three months, 6 of 37 (16.2%) had withdrawn because of safety reasons and intolerance to the study product. Three months and thereafter, 13 of 37 (35.1%) withdrew voluntarily.

The mean serum estradiol of both groups fluctuated from the baseline of 76.6 to 55.4, 56.7, 72.5, 69.2, 114.2 and 74.5 pg/ml at 1-, 2-, 3-, 4-, 5- and 6-month respectively. Whereas the mean serum follicle-

Table 1. Overall comparison of mean scale of modified climacteric indicators at admission, 1-, 3-, and 6-months.

Indicators	Admission		Month 1		Month 3		Month 6	
	Gr A n = 20	Gr B n = 17	Gr A n = 19	Gr B n = 17	Gr A n = 17	Gr B n = 15	Gr A n = 9	Gr B n = 9
Hot flushes	2.5	2.4	1.4	0.8	0.76	0.6	0.4	0.5
Night sweats	1.6	1.8	1.0	1.2	0.2**	0.73	0.4*	0.77
Headaches	2.2	2.5	1.2	1.7	1.0*	1.0*	0.8	0.8**
Mood instability	2.5	2.0	1.4	1.1	1.0	0.8	0.7*	1.1
Nervousness	2.4	2.5	1.5	1.6	1.05	1.0	0.8*	0.8**
Feeling neglected	1.2	1.0	0.42	0.8*	0.41	0.4*	0.3**	0.3
Excitable	2.1	1.7	1.4	0.88	0.9	0.86*	0.8	0.8
Insomnia	1.9	1.4	1.105	1.2**	1.11*	0.86	1.3#	0.88#
Feeling tired	2.2	1.8	1.7**	1.4	1.0	1.3**	1.2#	1.1
Back pain	2.4	1.9	2.0	1.2*	1.6*	1.1*	1.4	1.3
Joint pain	2.5	2.5	2.3	1.7	1.52	1.2	1.55	1.1*
Muscle pain	2.0	2.4	1.6	1.4	1.0	1.0	1.4	0.8
Dry skin	1.85	2.0	1.89#	1.6**	1.0	0.8	0.7	1.1
Dry vagina	1.4	0.8	1.0*	0.6	0.2**	0.6	0.4	0.1
Dyspareunia	0.8	0.5	0.7**	0.05	0.2*	0.13	0.3	0.0
Loss of sex satisfaction	1.25	0.8	1.26#	0.7**	0.8*	0.4*	0.5**	0.3
Loss of interest in sex	1.3	1.05	1.4#	1.0*	1.0*	0.4*	0.5**	0.1
Dysuria	0.9	0.5	0.4**	0.05	0.1**	0.06	0.0	0.0
Urinary frequency	1.3	1.2	1.2**	0.82	0.8*	0.8*	0.2	0.6
Urinary incontinence	1.4	1.0	0.9*	0.6**	0.94*	0.4	0.8	0.6
Total mean scale	35.6	32.6	26.6**	21.0**	17.2**	14.8**	15.1**	13.6**

* p-value < 0.05, ** p-value < 0.01, # Inverted significance of p-value.

stimulating hormone (FSH)/luteinizing hormone (LH) of both groups were slightly changed from baseline of 27.1/12.6 to 28.3/12.9 and 22.5/11.7 mIU/ml at 3- and 6- month respectively, are shown in Fig. 1. There were no statistical changes of hormonal profiles.

The mean cholesterol level was slightly altered from the baseline; corresponding with the mean HDL level. Whereas, the mean VLDL + LDL levels were slightly changed, concordant with cholesterol level. The mean triglyceride level fluctuated slightly from the baseline. There were no statistical changes of lipoprotein profiles, as shown in Fig. 2.

Blood pressure, pulse rate, and physical examination were performed monthly and no abnormal findings were detectable. The pelvic examination, Papanicolaou smear, breast examination, and electrocardiography were periodically performed, and no abnormal features were noted. All of the blood chemistry was in normal limits except; at the screening visit slight elevations were encountered in uric acid (1 case), and total bilirubin (1 case), while at follow-up visits a slight change was found in glutamic-oxaloacetic transminase (6 cases), glutamic-pyruvic transminase (5 cases), alkaline phosphatase (3 cases).

Around two thirds of the subjects, 25 in 37 cases (67.5%), did not completely adhere to the regimen, with frequency of at least once. Six cases (16.2%) reported vaginal spotting. Six cases (16.2%) discontinued due to intolerance of the adverse events or to perceived safety concerns.

Table 2. Characteristics of partial compliance to the therapy.

	No	%
Withdrew before three months (6)		
Intolerance to adverse effects	4	10.8
Safety reasons-development of transient hypertension	2	5.4
Withdrew at the third month or after (13)		
Voluntarily changed to another hormonal therapy	6	16.2
Unsatisfied clinical improvement	3	8.1
Intolerance to adverse effects	2	5.4
Safety reasons-development of transient hypertension	1	2.7
Move to other province	1	2.7

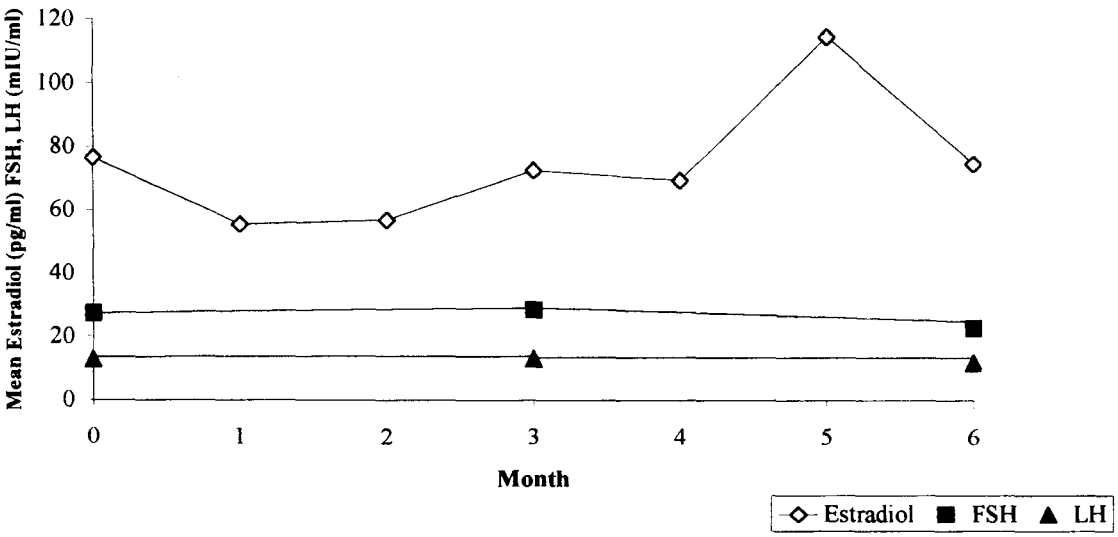

Fig. 1. Mean Estradiol, FSH, and LH from admission to month 6.

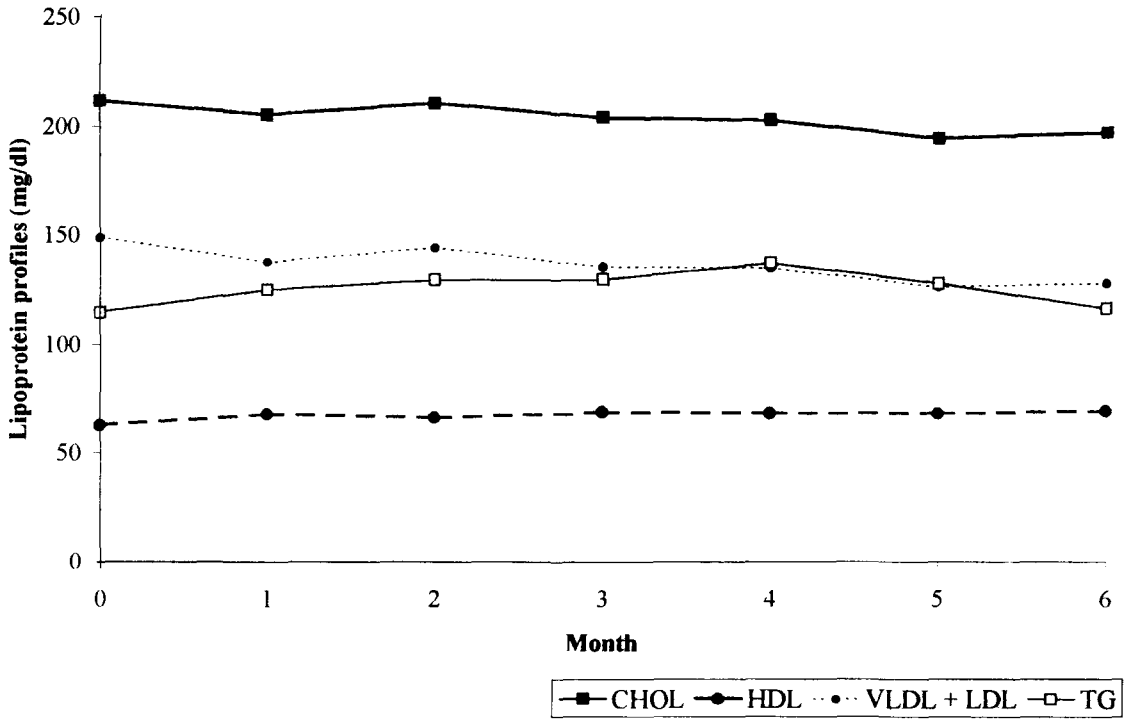

Fig. 2. Mean Cholesterol, HDL, VLDL + LDL and TG from admission to month 6.

At the end of the 6- month follow-up, there were two cases of myoma uteri. The first, having received a 50 mg capsule, was detected with myoma uteri and it was confirmed by ultrasonography to be a sub-serous myoma, 8.0 cm in diameter. The second, receiving a 100-mg capsule, had been palpated for a small uterine nodule at the 6- month visit. One case developed a small benign breast mass after the 3-month follow-up.

All adverse events, both related and remote conditions, are shown in Table 3. Six cases of vaginal spotting were suggested to have fractional curettage, and microscopic examination of the endometrium revealed no endometrial hyperplasia or overt malignancy.

DISCUSSION

This study modified the Greene climacteric scale, to be the clinical set of criteria for the diagnosis of climacteric syndrome[9]. Other unpleasant symptoms, urogenital and psychological symptoms were also evaluated. A score of 15 or more was considered to be estrogen deficiency, causing the clinical climacteric symptoms.

The overall climacteric performance scale was less than 15 in the 3- and 6-months of Group B, (100 mg daily regimen), while Group A, (50 mg) was not. The results in Table 1 demonstrate the efficacy of *Pueraria mirifica*, in that it significantly relieved or alleviated. In general, the 100 mg dose was relatively more beneficial than the 50 mg dose, in terms of overall scores. The 50 mg regimen was relatively more remarkable than the 100 mg regimen in alleviation of specific climacteric indicators. The efficacy of the therapy may not relate with the daily dose.

The two main vasomotor symptoms are hot flushes and night sweats. Hot flushes or flashes were experienced by 75 per cent to 85 per cent of all women undergoing natural menopause or who have undergone bilateral oophorectomies[10-12]. Some women require much higher doses of hormonal treatment

Table 3. Adverse events distributed by the study group.

	Gr A (n = 20)		Gr B (n = 17)	
	No	%	No	%
Mastodynia	8	40	5	29.4
Vaginal discharge	4	20	6	35.2
Vaginal Spotting	2	10	4	23.5
Headache	3	15	3	17.6
Dizziness	1	5	1	5.8
High blood pressure development	1	5	1	5.8
Myoma uteri development	1	5	1	5.8
Pelvic discomfort	1	5	1	5.8
Body itching	1	5	2	11.7
Anemia, Hemoglobin < 10.0 g/dl			2	11.7
Constipation			2	11.7
Benign breast cyst development			1	5.8
Chest discomfort			1	5.8
Menorrhagia			1	5.8
Nausea			1	5.8
Palpitation			1	5.8
Traumatic bone pain			1	5.8
Bitter taste	1	5		
Drowsiness	1	5		
GI discomfort	1	5		
Leg pain	1	5		
Insomnia	1	5		
Numbness of lower extremities	1	5		
Vaginal itching	1	5		
Vertigo	1	5		
Urinary frequency	1	5		

for alleviation of their symptoms; young, surgically oophorectomized women often need twice as much estrogen as those who have undergone physiologic menopause[13].

Although one study showed a relationship between circulating estrogen and the occurrence of hot flushes[14] most investigators have not found such a correlation[15,16]. In the present study, the subjects complained of a moderate to severe degree while the mean serum estradiol was relatively high, 76.6 pg/ml.

At the time of menopause, there is a shift in the lipid pattern, to one more similar to the pattern found in men, with increases in phospholipids, α-lipoproteins, and triglycerides[17]. The results of this study did not demonstrate changes in lipoprotein profiles, in the short-term of 6 months of follow-up. However, menopause seems to have only a slight effect on HDL cholesterol levels. Although estrogen replacement can not totally reverse this pattern, it does decrease LDL cholesterol concentrations and raises HDL cholesterol concentrations[18]. Natural estrogens increase the HDL2 and HDL3 fractions[19]. Thus, a long-term study of lipoprotein, among women consuming *Pueraria mirifica* with its phytoestrogen like effects, requires further evaluation.

Table 3 reveals comparable adverse events, along with other minor adverse effects. The most frequent complaint with PE's was mastodynia. The second most frequent adverse effect was vaginal discharge and vaginal bleeding. The frequency of irregular bleeding may be related to the non-adherence to the daily taking of the product or to withdrawal bleeding.

A small number of Perimenopausal women were treated with *Pueraria mirifica*, and with a high rate of loss follow-up in the present study there was significant improvement in the modified Greene climacteric scale and its parameters, with transient abnormal blood profiles in a small number of the subjects. *Pueraria mirifica*, with a biological activity similar to estrogen, showed significant promise in the treatment of vasomotor symptoms among perimenopausal women.

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ประสิทธิผลและความปลอดภัยของกวาวเครือขาว (*Pueraria mirifica*) สำหรับการรักษาอาการ Vasomotor ในสตรีวัยหมดระดู : การศึกษาระยะที่สอง

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วัตถุประสงค์ : เพื่อประเมินประสิทธิผลและความปลอดภัยเบื้องต้นของกวาวเครือขาว (*Pueraria mirifica*) สำหรับการรักษาอาการ vasomotor ในสตรีวัยหมดระดู

การออกแบบ : การศึกษาแบบปลายเปิด

สถานที่ : โรงพยาบาลศูนย์หาดใหญ่

ผู้เข้าร่วมการศึกษา : หญิงก่อนและหลังวัยหมดระดูที่มีอาการ vasomotor เช่น ร้อนวูบวาบตามเนื้อตามตัว เหงื่อออกกลางคืน รวมถึงอาการของระบบปัสสาวะ ระบบอวัยวะเพศ

วัสดุและวิธีการ : ผู้เข้าร่วมการศึกษาได้รับการสุ่มโดยความสมัครใจเพื่อได้รับกวาวเครือขาวชนิดแค็ปซูลขนาด 50 และ 100 มิลลิกรัม รับประทานวันละ 1 ครั้ง ก่อนนอน เป็นเวลา 6 เดือน

ผลการศึกษา : อาสาสมัครทั้งหมด 48 ราย มี 11 รายตัดออกจากการศึกษาไม่สามารถติดตามผลการศึกษาได้ ที่เหลือจำนวน 37 ราย กลุ่มเอได้รับกวาวเครือขาววันละ 50 มิลลิกรัม จำนวน 20 ราย (ร้อยละ 54.1) และกลุ่มบีได้รับกวาวเครือขาววันละ 100 มิลลิกรัม จำนวน 17 ราย (ร้อยละ 45.9) กลุ่มเอค่าเฉลี่ยของ modified Greene climacteric score ลดลงจาก 35.6 เป็น 26.6, 17.2 และ 15.1 ส่วนกลุ่มบีลดลงจาก 32.6 เป็น 21.0, 14.8 และ 13.6 ในเดือนที่ 1, 3 และ 6 ตามลำดับ ค่าเฉลี่ย serum estradiol แปรผันจากเมื่อแรกรับ 76.6 เป็น 55.4, 56.7, 72.5, 69.2, 114.2 และ 74.5 pg/ml ในเดือนที่ 1, 2, 3, 4, 5 และ 6 ตามลำดับ ค่าเฉลี่ยของ serum follicle-stimulating hormone (FSH)/luteinizing hormone (LH) คงที่ระหว่าง 27.1/12.6, 28.3/12.9 และ 22.5/11.4 mIU/ml เมื่อแรกรับ เดือนที่ 3 และ 6 ตามลำดับ

สรุป : กวาวเครือขาวเป็นพืชที่มีเอสโตรเจนสามารถบรรเทาอาการ climacteric ของหญิงก่อนและหลังวัยหมดระดูได้ ผลลบข้างเคียงเกิดขึ้นชั่วคราวในอาสาสมัครจำนวนหนึ่งได้แก่ ภาวะซีดและน้ำย่อยตับเพิ่มขึ้น ในขณะที่ไขมันโปรตีนและฮอร์โมน เพิ่มขึ้นเล็กน้อย แสดงว่ากวาวเครือขาวมีหลักฐานสำคัญในการรักษาอาการ climacteric ของหญิงก่อนและหลังวัยหมดระดู อย่างไรก็ตาม ขนาดที่เหมาะสมที่จะใช้ทางคลินิกควรประเมินการตอบสนองเป็นการเฉพาะราย

คำสำคัญ : กวาวเครือขาว, อาการของวัยหมดระดู, หญิงก่อนและหลังวัยหมดระดู, พืชที่มีเอสโตรเจน

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