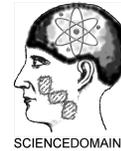




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Evaluation the Effects of VitB6 on the Treatment of Premenstrual Syndrome: A Clinical Randomized Trial

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Authors' contributions

This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.

Original Research Article

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ABSTRACT

Introduction: Premenstrual syndrome (PMS) is a regularly appearance number of symptoms during luteal phase of menstruation. The purpose of this study was, determination the effect of Vit B6 on treatment this syndrome.

Method: Two hundred girls who had moderate and severe form of premenstrual syndrome, selected randomly and divided in two groups. First group received 40 mg Vit B6 daily for three months and, and second group received daily one tablet of placebo for three months. Also they filled Rosignol Bonlender check list during use of drug. Data analyzed by SPSS version 19 and severity of symptoms compare before & after intervention in each group, and after treatment in two groups.

Result: Severity of physical, mental, physical and mental symptoms in patients who receive Vit B6 and placebo had reduced ($p < 0.05$).

Conclusion: Vit B6 is effective on PMS.

Keywords: PMS; Vit B6; treatment.

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1. INTRODUCTION

For many century, premenstrual syndrome (PMS) is a regularly appearance groups of symptoms during luteal phase of menstrual cycle also the etiology of it is unknown [1-4]. The most common physical and emotional symptoms are breast tenderness, headache, backache, and lack of energy, clumsiness, tension, anxiety, irritability, depression, food craving, bloating and changes in sexual drive [3,5-8]. About 80% women in reproductive age suffer of these symptom [9-14] and 3% -9% of them suffer severe form of PMS [15-16]. In addition these symptoms have negative effect on quality of life, also the repercussions on economic costs resulting predominantly from a reduction in reproductively [17]. Boghrat (an iranian scientist) describe these symptoms before bleeding [18] and at first time this syndrome was described in 1931 by frank and horney [17,19]. Several treatments for pms have been proposed. The usual treatment for PMS are: Education, supportive counseling [20] and general self care measures such as increase and adoption of a helpful diet. Also for women with severe form of PMS can use fluoxetine, anxiolytic drug alprazolam, oral contraceptive, no steroidal anti inflammatory drugs, spirinolactone, gonadotropin – releasing hormone agonists [9]. One of the most current treatment in pms is pyridoxine (vit b6), it was thought to correct estrogen metabolism and can regulate the brain monoamine production (helen 1989) and it is a factor in the final stages of serotonin and dopamine synthesis [21]. Many studies suggested beneficial effect of vit b6 on treatment PMS [18,22] and their results are not certainly. This study was done to compare the effect of vit b6 and placebo on treatment of PMS in Islamic azad university sari branch, 2012.

2. METHODS

This study was a double blind clinical trial study that compares with placebo for evaluation the effect of them on treatment premenstrual syndrome. We had coded the drugs for blinding; my coworker coded the drugs and I prescribed them to samples. After confirm of this study by Ethic committee of Islamic azad university sari branch, all girl students of this university entered in our study. They filled Rosignol Bonlender questionnaire (for three months) to assay PMS. This questionnaire was standard check list for assay severity of PMS (validity and reliability of this questionnaire had demonstrated previously).

First section of this check list was about physical symptoms and second section was a bout mental symptoms. The severity of each symptom was characterized with 4 scores (0, 1, 2 and 3). Score 0 means: don't have any symptoms, score 1 means: the people have symptoms but don't have any effect on their activity, score 2 means: the symptoms effect on their activity, score 3 means: the symptoms induced disability in their life. We considered sum of severity of physical & mental symptoms, if the mean of this score during 3 months was equal or higher than 17, the intensity of this symptom was moderate and severe form.

2.1 Inclusion and Exclusion Criteria

The inclusion criteria of this study were: single girls, age between 18-30 years old, have regular menstruation, duration of cycle between 21-35 days and have moderate and sever form of premenstrual syndrome according standard measurement (Rosignol Bonlender check list).

Also, the exclusion criteria were: breast feeding, use of hormonal contraceptive, have a history of psychological disease such as depression, accrue traumatic problem during last 2 months, using drug such as anti depression and herbal medicine during six months ago.

2.2 Subject

Two hundred girls who had moderate and severe form of PMS, selected and divided in two groups, randomly (Fig. 1). According to $\alpha=0.2$, $p=0.433$, $b=0.2$ and $p=0.05$, 31 girls in each group was calculated, but for preventing release of samples, we decided, forty girls for each group. First group received 40 mg Vit B6 (that produced by the Iranian hormone –Tehran company) daily for three months and, second group received daily one tablet of placebo (starch tablet, that produced by Razi hospital pharmacy-Iran) for three months also consent form was signed by the patients. They filled Rosignol Bonlender check list during use of drug. The duration of fill the questionnaire and collection the data was between marches 2012 to October 2012. We had visited samples once a month for giving drug to them and check the situation of complete the questionnaires, to confidence if they fill it correct or not. Finally severity of physical symptoms, mental symptoms, physical and mental symptoms after receiving drug had compared. We had used SPSS version 19, for analysis, and depended T test, manwitny U test regarding matching of groups for quantitative & qualitative variables, respectively. Wilcoxon test had used for comparing severity of symptoms before and after treatment in each group. Man witny U test had used for comparing severity of symptom after treatment in two groups. (The registration number of this study: IRCT2012123010705N1).

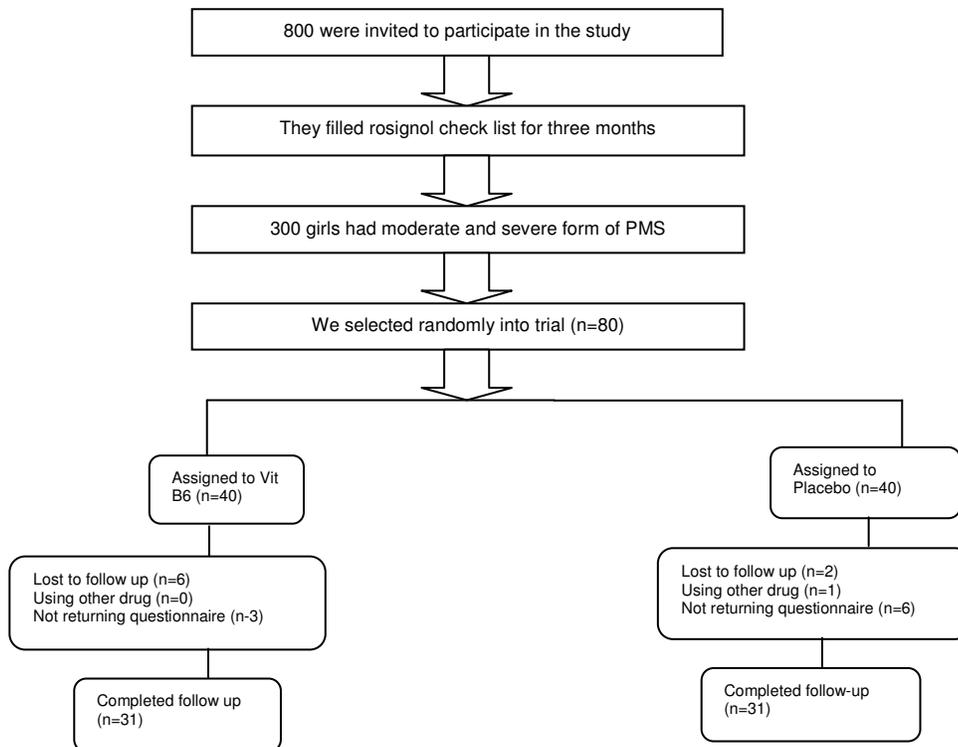


Fig. 1. Flowchart of entering the subjects

3. RESULTS

One hundred and fifty five girls who had moderate and sever form of premenstrual syndrome divided in 2 groups (each group: 31 girls). Mean age of girls who used Vit B6 was (23.19 + 2.1) and (22.4+1.9) respectively. Table 1, show the comparison two groups regarding some confounding variables such as; age, BMI, field of education, level of education, severity of physical , mental , physical and mental symptoms before intervention in two groups. It shows that, we don't have significant difference between two groups.

Table 1. Comparison two groups regarding some confounding variables

variables	P value
age	0.5
BMI	0.9
Field of education	0.9
Level of education	0.2
Severity of physical symptom before treatment	0.3
Severity of mental symptom before treatment	0.8
Severity of PMS before treatment	0.3

Table 2, shows the effect of drugs in each group and comparing of then in both group.

Table 2. Comparison the severity of symptom after treatment

Variables	Vit B6	Placebo	Vit B6 versus placebo (P value)
	Before treatment versus after treatment (P value)	Before treatment versus after treatment (P value)	
Severity of Physical symptoms	0.000	0.03	0.007
Severity of Mental symptoms	0.000	0.01	0.1
Severity of PMS	0.000	0.001	0.008

This table shows that, significant differences were seen in both groups after treatment. Also comparison severity of symptoms after intervention, show significant difference just regarding physical, physical and mental symptoms.

4. DISCUSSION

PMS is cyclic recurrence of group symptoms, which occurs in luteal phase, and repeated monthly, in severe form of PMS, it can interfere with some aspect of lifestyle. About 25% - 50% of women in reproductive age suffer this syndrome [23]. According to similar studies, many confounding variables can effect on this syndrome such as: age, BMI, marriage statuses, field of education, and level of education and place of residency; so we matched these groups along these variables.

In group with receiving Vit B6, significant effect were seen regarding their physical , mental symptoms ,and their physical and mental symptoms after treatment. During in 1970, a study

reported the benefit effect of Vit B6 on depression. Vit B6 is a cofactor in the synthesis of neurotransmitters and it is a reasonable basis for its role in alleviation mental symptoms of PMS [9]. A study was done in Iran showed, efficacy of Vit B6 on premenstrual symptoms [18]. Another study showed pyridoxine is effective on just emotional symptom of PMS [24]. Maybe different dose of Vit B6 between this research and our study, ended to different effect of Vit B6 on physical symptoms. In our study the group treated with placebo had significant improvement in severity of symptoms. The placebo effect in reducing the severity of symptoms expressed in other studies (as a placebo effect), even in control group that didn't receive any placebo, just filled the daily checklist reducing the severity of symptoms were seen [25].

In this study we assay collection of physical and social symptoms. It was better we assay each symptom (such as: Depression, anxiety, headache...) before and after treatment. We suggest doing a study in future to comparison herbal medicine with current treatment.

5. CONCLUSION

Vit B6 is effective treatment on physical and mental symptom of PMS also, the placebo effect were seen in treatment of PMS.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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