

## Original Research Article

### Comparison of the effect of vaginal capsule of evening primrose oil and misoprostol on cervical ripening of nulliparous women with post-term pregnancy: A clinical Trial

#### Abstract

**Background and objective:** Prolonged pregnancy refers to situations where pregnancy lasts for more than 42 weeks from the first day of the last menstruation. The present study was conducted in order to compare the effect of vaginal capsule of evening primrose oil and misoprostol on cervical ripening of nulliparous women with post-term pregnancy.

**Materials and Methods:** The present clinical trial study was conducted on 130 pregnant women with prolonged pregnancy referring to the delivery department of Besat Hospital in Sanandaj. Samples were randomly assigned to groups, with the intervention group receiving 500 mg evening primrose oil vaginal capsule and 25 micrograms of sublingual misoprostol, and the control group receiving a placebo-vaginal capsule and 25 micrograms of misoprostol sublingually. Required data was collected by demographic questionnaire and Bishop Checklist; the collected data was analyzed using SPSS version 21 and Chi-square, T-test, covariance analysis, one-way ANOVA, and repeated measures.  $P < 0.05$  was considered significant.

**Results:** The results showed that the mean Bishope scores of the subjects in the intervention group were significantly higher than the control group ( $p < 0.05$ ). There was no significant difference in uterine contractions, fetal heart rate and vital signs between two groups ( $p > 0.05$ ).

**Conclusion:** The results of the present study showed that vaginal capsule of evening primrose oil is effective on the rate of cervical ripening in post-term pregnancies. Also, no significant effect on was observed on fetal heart rate, uterine contractions, and vital signs of the mother.

**Keywords:** vaginal evening primrose oil, misoprostol, cervical ripening, post-term pregnancy, Bishop score

## **Introduction**

Pregnancy is a new and unique situation (Babanazari, 2017). Based on the gestational age, it is divided into three categories of preterm, term, and post-term (Cunningham, 2014). Prolonged pregnancy refers to situations where pregnancy lasts for more than 42 weeks from the first day of the last menstruation (Behdani, Begi, & Mobaraki, 2008). The prevalence of prolonged pregnancies is 4-19%. The most common cause of pregnancy is a mistake in determining the gestational age (Cunningham, 2014; Giahi, 2013); other causes include embryonic ones (anencephaly, adrenal hypoplasia, pituitary insufficiency or placenta sulfatase deficiency), which can reduce estrogen and postpone delivery. Also unripened cervix is a significant maternal cause (Eslamian, Shahsavar, 2007).

Prolonged pregnancy face has some risk, including psychological stress, physical injuries due to the delivery of large babies, postpartum hemorrhage in uterus, postpartum infection and long-term hospitalization (Azarkish et al., 2008). For the termination of pregnancy in prolonged cases, two methods of induction of labor following cervical preparation or cesarean are used (Ahmadi et al., 2013; Crane, 2006)

Factors that can predict the probability of induction include maternal factors (number of births, age, weight, height, and body mass index), fetal factors (birth weight and gestational age) and cervical status (Bajpai et al., 2015). Induction of labor in cases where the cervix is not ready can reduce the success of normal delivery and increase the probability of cesarean section (Movahed et al., 2015). The most commonly used cervical examination method was introduced by Bishop in 1964 under the name of Bishop scoring method. This score was based on five components (dilatation, effacement, condition and strength and display station of the organ) (Shahoie et al.,

2016). Scores higher than 9 show the highest level of cervical preparation and those lower than 4 suggest undesirable cervical status (Zargar et al., 2014; Jahdi et al., 2016).

So far, several methods have been proposed to help soften the cervix and prepare it before induction of childbirth, which are mainly classified in two groups of mechanical and biochemical (Levey, Arslan, & Funai, 2006).

Mechanical techniques include the application of a trans-cervical catheter with or without normal infusion of normal saline (Karjane, Brock, & Walsh, 2006), hygroscopic dilators and stripping of membranes (Keshavarzi et al., 2012). Pharmaceutical methods include prostaglandin, oxytocin, and estrogen. Among the available medications, prostaglandins play an important role in inducing labor, Misoprostol and dinoprost are most commonly used. Misoprostol is both vaginal and oral, and it is widely used for induction of childbirth due to its favorable price and high effect (Inal et al., 2015). However, Misoprostol has maternal and fetal complications (Alamiherandi, Karamali, & Moieni, 2012).

Nowadays, in addition to medical treatments, some traditional methods such as various forms of medicinal plants, including evening primrose oil, are used to help prepare cervix (Jahdi et al., 2016).

Evening primrose is a 2-year old wild plant with yellow flowers that grows in northern America and some parts of Europe and belongs to *Urtica* family (Tahermanesh et al., 2015; Takfalah et al., 2009). The oil of evening primrose flower is extracted from the seeds of this plant (Michael, 2008) and contains two essential fatty acids (linoleic acid and gamma-linolenic acid). These fatty acids facilitate the synthesis of prostaglandin misoprostol, as well as the softness and sufficient dilation of the cervix (Cunningham, 2014; Begi, Kazemipur, & Tabarestani, 2010).

Evening primrose oil is generally tolerated by humans. Therefore, there is no limit to its use during pregnancy because it does not interfere with biophysical profiles and stress tests. Also, it is easy to use and does not require hospitalization and continuous monitoring of the fetus (Jahdi et al., 2016; Bayles, Usatine, 2009). There are controversial studies regarding the effect of evening primrose oil on cervical condition. Tahermanesh et al reported that vaginal capsules of

evening primrose oil are effective in cervical ripening , and this medication is readily available, inexpensive and has no significant side effects (Tahermanesh et al., 2015). The use of vaginal capsule of evening primrose oil can be effective in improving cervical profile and its ripening before applying genecology (Rusinne, Verano, 2015). A retrospective study reported that oral administration of evening primrose oil from 37 weeks of gestation until the beginning of labor did not only result in a reduction in the length of pregnancy and labor, but also it caused a slight increase in the prevalence of prolonged rupture of membranes , prolonged uterine contractions, stopping the fetus from descending further and the use of vacuums (Dove, Johnson, 1999). According to the results of Jehadi et al. (2016) study, the use of evening primrose oil capsules did not change the Bishop score significantly.

The present clinical trial study was conducted on 130 pregnant women with prolonged pregnancy referring to the child birth wardt of Besat Hospital in Sanandaj in 2018.

## **Materials & Methods**

The present randomized, one-blind clinical trial was conducted on all nulliparous women with post-term pregnancy admitting to maternity ward of Besat Hospital in Sanandaj in 2018. The inclusion criteria were nulliparous, willingness to participate in the study, being healthy, lack of contraindications for the use of evening primrose oil, non-indications of misoprostol use, no structural cervical anomalies, 40 weeks and 6 days of gestational age based on the date of the first day of the last menstruation or the first trimester ultrasonography, single-pregnancy, live fetus, vertex fetal presentation, normal heart embolism pattern, absence of uterine contractions, Bishop score lower than or equal to 4, Intact membranes, normal non stress test, maternal height over 150 cm, non-addiction, including non-sterility test, the estimated weight of fetus between 2500-4000 grams.

Exclusion criteria were using enema or laxative, using herbal medication prior to study, mother's unwillingness to continue cooperation in the research, the need for cesarean section during study, the development of possible side effects of the medication such as headache, nausea, diarrhea, fever, shortness of breath, contractions, abnormal uterus and abnormal pattern of fetal heart rate.

The researcher referred to the child birth ward of the center and selected 130 nulliparous women with prolonged pregnancy who had the criteria for entering the study. In order to observe ethical considerations, after giving explanations about the objective and process of the study to the pregnant mothers, their written consent informed consent was obtained. The subjects were randomly Coin closed envelopes divided into two groups of intervention (evening primrose oil and Misoprostol) and control (Misoprostol and placebo). Required data was collected using a three-part questionnaire. The first part was related to the demographic characteristics of the mother (age, education, occupation, place of residence), the second part was related to the observer's specification (abortion, gestational age, bishop score, admission, estimated fetal weight). The third part was completed to record Bishop Score, evaluate uterine contractions, fetal heart rate and vital signs of the mother. The demographic information questionnaire was completed and a preliminary clinical examination including maternal vital signs, uterine contractions, non-stress test and bishop score, was performed by the research collaborator for all samples. The initial Bishop score was recorded in the relevant table by the researcher.. In the intervention group 500-mg capsule of evening primrose oil was pierced by a sterilized needle and implanted vaginally into posterior fornix. After the insertion, the woman was advised to stay on bed for 30 minutes, sleep on the left side and not leave the bed. At the same time, 25 micrograms of misoprostol was given to the mother by sublingually. The fetal heart rate was recorded every 15 minutes after the implantation of the capsule. After 6 hours, the Bishop score was evaluated again by a collaborator research who was not aware of the classification of the subjects, and the obtained value was recorded by the researcher in the relevant table. If the Bishop score was less than 9 and effective uterine contractions (3 contractions with 40 seconds duration), and the heart rate was normal, a maximum of two other doses (a 500-mg evening primrose oil vaginal capsule with 25 µg sublingual misoprostol) was repeated every 6 hours and the Bishop score was evaluated. After the second dose, if the Bishop score increased or uterine contractions started, the third dose would get cancelled and the intervention would end. Subjects in the control group were given a 25-microgram sublingually by a researcher and an empty capsule (placebo) was placed vaginally in the posterior fornix. After the insertion, the woman was advised to stay on bed for 30 minutes, sleep on the left side and not leave the bed. At the first hour after the administration of misoprostol, the fetal heart rate was evaluated and recorded by the researcher every 15 minutes. Then, 6 hours after the intervention, the Bishop score was re-

evaluated by a collaborator research and recorded in the relevant table. If the Bishop score was less than 9 and effective uterine contractions (3 contractions were not initiated with 40 seconds duration) and the fetal heart rate was normal, two other doses were repeated every 6 hours, and the Bishop score was evaluated and recorded again. After the second dose, if Bishop Score increased or uterine contractions started, the third dose would get cancelled and the intervention would end. Finally, the collected data was analyzed with SPSS 21 using Chi-square test, independent t-test, covariance analysis, one-way ANOVA, and repeated measures. This study was approved by Ethics Committee of Kurdistan University of Medical Sciences with ethics code of (ir.muk.rec.1396 / 36) and registering the proposal in the IRCT.ir system with the code (29852).

## Finding

According to the results of the present study, the mean age of the samples was 27.97 years. The majority of the subjects (38.5%) had a diploma. Most of them (93.8%) were housewives and mostly (70%) lived in the city. 13.8% of the subjects in the intervention group and 4.5% in the control group had history of abortion, and 4.5% of the intervention group and 3.8% of the control group reported curettage history. The mean estimated fetal weight was 3441.53 grams in the intervention group and 3480.00 g in the control group (Table 1).

**Table 1. Demographic characteristics of subjects**

	Characteristics	Frequency and percent
<b>Age</b>	<20	3 (2.3%)
	20-24	36 (27.6%)
	25-29	41 (31.5%)
	30-34	35 (27)
	≥35	15 (11.6%)
<b>Education</b>	Illiterate	3 (2.3%)
	Primary school	40 (30.8%)
	Secondary school	24 (18.4%)
	Diploma	50 (38.5%)
	Academic education	13 (10%)
<b>Occupation</b>	Housewife	122 (93.8%)
	Employed	8 (6.2%)

<b>Residence</b>	Urban	91 (70%)
	Rural	39 (30%)
<b>Gestational age</b>	40-41±6	109 (83.9%)
	≥41	21 (16.1%)
<b>History of abortion</b>	Yes	25 (19.2%)
	No	105 (108.8%)
<b>Curettage history</b>	Yes	12 (9.2%)
	No	118 (81.8%)

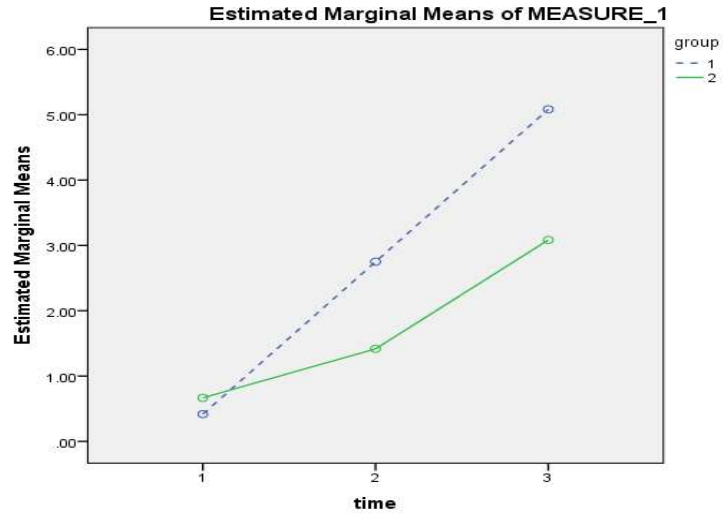
In regard with Bishop Score, the results showed that was no significant difference two groups before intervention, and both groups were homogeneous ( $p = 0.73$ ) (Table 2). However, there turned out to be a significant difference between two groups after intervention ( $p < 0.05$ ) (Table 3,4 & Figure 1).

**Table2. Comparison of the mean and SD of Bishop Score of the two groups under study**

<b>Group</b>	<b>Intervention</b>	<b>Control</b>	<b>P value</b>
<b>Score</b>			
<b>Before intervention</b>	0.41±0.51	0.66±0.65	0.73
<b>6 hours after intervention</b>	2.75±1.28	1.41±0.71	<0.05
<b>12 hours after intervention</b>	5.08±1.62	3.08±1.72	<0.05

**Table3. Comparison of the mean and SD of Bishop Score of the two groups under study before and after intervention**

<b>Time</b>	<b>Before intervention</b>	<b>6 hours after intervention</b>	<b>12 hours after intervention</b>	<b>p-value</b>
<b>Group</b>				
<b>Intervention</b>	0.41±0.51	2.75±1.28	5.08±1.62	<0/05
<b>Control</b>	0.66±0.65	1.41±0.71	3.08±1.72	<0/05



**Figure 1. The progression of Bishop Scores in two groups during time**  
**Group1. Intervention group      Group 2. Control group**

The results of the study did not show a significant difference between two groups in regard with fetal heartbeat ( $p = 0.57$ ). (Table 3). The mean and standard deviation of uterine contractions was  $3.45 \pm 0.72$  in the intervention group and  $3.39 \pm 0.87$  in the control group, which was not statistically significant ( $p = 0.67$ ).



The findings showed that there was no significant difference between the two groups in regard with vital signs of hypertension ( $p=0.6$ ), pulse ( $p=0.16$ ), respiration ( $p=0.15$ ), and temperature ( $p = 0.10$ ).

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**Table 4. Comparison of mean and standard deviation of fetal heart rate in the studied groups**

Fetal hear rate	Intervention group	Control group	P value
First 15 minutes	139.24± <b>6.05</b>	138.50± <b>6.59</b>	0.57
First 30 minutes	138.56± <b>8.02</b>	140.26± <b>8.01</b>	
First 45 minutes	139.50± <b>10.05</b>	142.12± <b>8.5</b>	
First 60 minutes	159.61± <b>15.9</b>	144.73± <b>9.58</b>	

## Discussion

The present study was conducted in order to compare the effect of vaginal capsule of evening primrose oil and misoprostol on cervical dilation of nulliparous women with post-term pregnancy. Based on statistical analysis, there was no significant difference between two groups in Bishop Score before the intervention ( $p = 0.73$ ). However, the mean Bishop score of the intervention group was significantly higher than the control group after the intervention ( $p = 0.00$ ).

According to the results of Khatami et al. (2018) study, entitled "The effect of vaginal consumption of evening primrose oil on cervical preparation in nulliparous women with post-term pregnancy", vaginal administration of evening primrose oil reduced the duration of the latent phase and had a positive effect on cervical softness. Also, the results of Alessandra et al. (2006) study, the administration of 3 capsules of oral primrose oil a day for one week show that there was effective on the Bishop Score and cervical length of pregnant women in term labor. These two study are consistent with the results of the present study.

Tahermansh et al. (2015) study assessed the effect of evening primrose oil on cervical ripening and dilation of the cervix before hysteroscopy operation. The intervention group received 1000 mg of evening primrose oil in the posterior fornix, in two capsules each containing 500 mg, 6-8

hours before the operation of the hysteroscopy, and the placebo group received the same capsules which, actually, contained sterilized water. The mean duration of cervical dilatation was significantly lower in the group receiving the drug in comparison with the placebo group ( $p = 0.003$ ) (19). Also, Rossini et al. (2015) study investigated the effects of evening primrose oil on cervical ripening prior to gynecologic procedures. In the end, it was concluded that receiving 4 capsules of evening primrose oil before applying gynecology could be effective in improving the cervical profile and its achievement. Aquino et al. (2011) study investigated the ease of cervical dilatation in postmenopausal women and premenopausal nursing mothers who received vaginal evening primrose oils prior to hysteroscopy operation. In this study, 2 capsules (1000 mg) of evening primrose oil were inserted into the posterior fornix of the vagina at 4-6 hours prior to hysteroscopy operation, and the cervical dilatation rate was assessed using a Hagar dilator. The results indicated that cervical dilatation was significantly facilitated in all patients who received evening primrose oil.

The results of these three studies are consistent with the results of the current study and show the positive impact of evening primrose oil on the amount of cervical ripening. This medication is also available, inexpensive, and has no significant side effects. The Bishop score of participants in the intervention group was significantly higher than the control group, indicating the effectiveness of the drug in ripening the cervix. Further more, the results indicated that vaginal administration of evening primrose oil had no significant effect on fetal heart rate, uterine contractions and vital signs of the mother.

On the other hand, according to the results of Jahdi et al. (2016) study, which was conducted on the effect of oral capsules of evening primrose oil on cervical dilation of pregnant women, oral administration of evening primrose oil in pregnant women with gestational age (40 weeks to 40 weeks and 6 days) did not change the Bishop score significantly. More over, in a retrospective study by Dove et al. (1999) oral administration of evening primrose oil from 37 weeks of pregnancy to delivery not only did not reduce the length of pregnancy and labor, but also increased the incidence of prolonged rupture of membranes, strengthened uterine contractions, stopped fetal descent, and enhanced the use of use of vacuums. The inconsistency between the results of these studies and the current study can be due to differences in drug use patterns, In these studies using oral administration but the current study using vaginal administration of the

evening primrose oil. This study was also performed at 40 weeks and 6 days and more of gestational age, while Jahdi's study was conducted at 40 weeks to 40 week and 6 days gestational age. In Dove's study, oral administration of evening primrose oil was performed from 37 weeks of pregnancy to delivery.

Several studies have been conducted on the effective dose of misoprostol, according to the results of which 25 micrograms every 4 to 6 hours is the best and most efficient dose (Martin, Hamilton, 2003), which is quite consistent with the results of the present study.

according to the results of Abedi et al. study, which was conducted to compare the effect of vaginal misoprostol and intra-cervical Foley catheter on cervical ripening before induction. The total time of beginning of induction to labor was similar in both groups (Abedi asl et al., 2005). However, Same with Jadish's study (Jadish et al., 2003), Tachycardia, Excessive uterine stimulation and need for sedative (pethidine and promethazine) were observed in the misoprostol group. Additionally, the results of Sotoudenia et al study (Sotodenia, 2012), which was conducted to compare the effect of vaginal misoprostol and oral castor oil on the induction of labor, indicated that abruption, tachycardia, and the hospitalization of the infant in NICU were the main side effects of misoprostol, while nausea and diarrhea were the only side effects of castor oil.

According to the results of the present study, both groups showed no abnormalities in fetal heart rate, uterine contractions and vital signs of mother. Therefore, evening primrose is a safe flower and according to various studies, it is generally tolerated by people. Therefore, there is no limit to its use during pregnancy, because it has no effect on the safety of the fetuses monitored by the biophysical profile test and non stress test. Also evening primrose oil is quite cheaper than misoprostol And does not have misoprostol side effects include abruption, tachycardia, and the hospitalization of the infant in NICU (Jahdi et al., 2016; Bayles, Usatine, 2009). Therefore it seems that the application of evening primrose oil is much more reasonable.

Being conducted on nulliparous women and not considering women with multiple pregnancies are the main limitations of the present study. Therefore, it is suggested to conduct further studies to provide more comprehensive results and findings.

Since the use of herbal and complementary medicine is very important, using a larger sample size and comparison of herbal medicine and chemical drugs and the use of non-pharmaceutical methods is, also, recommended.

## Conclusion

The results of the present study showed that vaginal capsule of evening primrose oil is more effective than misoprostol in cervical ripening and Bishop Score. Also, it does not affect the heart rate of the fetus, uterine contractions, and vital signs of the mother. Therefore, it can be used as an appropriate substitute for misoprostol for cervical ripening.

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