

Tabriz University of Medical Sciences
Nursing & Midwifery Faculty

Dissertation submitted for Master of science in midwifery

Title: **The effect of oral Mullein capsule (*Verbascum Songaricum*) on uterine leiomyomas size and the amount of menstrual bleeding in women with asymptomatic leiomyomas: a triple blind randomised controlled trial**

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Abstract

Introduction: Myomas are the most common benign tumors of uterus. Although the treatment of asymptomatic uterine myomas is rarely recommended, the plausibility of symptomaticity makes the use of pre-emptive measures reasonable.

Objectives: To evaluate the effect of oral Mullein capsule on asymptomatic uterine leiomyomas size and the amount of menstrual bleeding

Methods: In this two-parallel arm triple-blind, randomized, controlled trial, fifty 18-50-year-old women, with at least a confirmed asymptomatic myoma greater than 2.5cm were selected among women referring to the clinics affiliated to Tabriz-Iran University of Medical Sciences, and randomized in one of the two groups. The first group (n=25) received Mullein (*Verbascum*) powder capsules, 400mg, and the second group (n=25) received placebo capsules, 400mg twice a day for 8 weeks. The random allocation sequence was determined based on a randomized block design and a ratio of 1:1. The primary outcomes of this study were the myoma size (measured using ultrasound) 8weeks after treatment and the menstrual blood loss (measured using pictorial blood loss assessment) 4 and 8weeks after intervention. The participants, the researcher, and the outcome assessor (radiologist) were blinded.

Results: Three participants in placebo group withdrew from the study; however, their clinical data was included in the final analysis. After the intervention, the mean volume of the largest myoma reduced from 94.1 ml to 87.2 ml in the Mullein group and increased from 121.8 ml to 122.8 ml in the placebo group, indicating no statistically significant difference (adjusted mean difference (aMD) = -7.6 ml, 95% CI: -22.0 to 6.6). Within-group analysis of the largest myoma volume showed a significant reduce in the Mullein group (MD = -6.8 ml, 95% CI: -13.0 to -6.3). There was no significant between-group difference in menstrual bleeding during the two-month intervention period in the first (aMD=1.3, 95% CI: -24.3 to 27.0) and second (aMD =7.3, 95% CI: -12.6 to 27 .2) treatment cycles. However, the Within-group analysis showed a significant increase in the first cycle of menstrual bleeding in the Mullein group after the intervention (MD =17.3, 95% CI 1.4 to 33.1). There was no serious side effect during treatment course.

Conclusion: The results of this study showed that 800mg oral dose of Mullein capsule per day for 2 months did not affect the myoma size, and intensity of menstrual bleeding, although there was a significant decrease in the size of myoma in the Mullein group.

Keywords: Mullein capsule; *Verbascum Songaricum*; Uterine leiomyoma; fibroid; menstrual bleeding

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