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Investigating the effect of vitamin D vaginal suppository on sexual function among postmenopausal women: study protocol for a randomized controlled trial

Zinat Sarebani[1], Zainab Alimoradi[2*], Ehsan Aali[3], Monirsadat Mirzadeh[4], Venus Chegini[5], Mohammadreza Abbaspour[6] and Mark D. Griffiths[7]

Abstract

Background: Menopause is associated with changes in sexual function which are partly due to vaginal atrophy in response to estrogen reduction. Estrogen administration temporarily reduces the symptoms of vaginal dryness, but long-term exposure to this drug is likely to be associated with serious complications. Considering the promising results of previous studies concerning the effect of vitamin D on vaginal dryness, the proposed study will investigate the effect of vitamin D vaginal suppository on the sexual function of postmenopausal women.

Methods: In a randomized, controlled clinical trial, 105 postmenopausal women will be randomly assigned to three groups receiving vitamin D vaginal suppository, placebo vaginal suppository, or control (no intervention). Vitamin D vaginal suppositories contain 1000 units of vitamin D3. The timing of the use of vitamin D vaginal suppositories and placebo suppositories will be every night in the first 2 weeks, and every other night in the following 6 weeks (8 weeks in total). The primary outcome will be the sexual function of participants which will be assessed using the Female Sexual Function Index (FSFI) before and immediately after the intervention, and at 1 and 2 months after the end of the intervention. The side effects of these suppositories will be examined as a secondary consequence of the study. Data will be analyzed using SPSS software version 25. In the case of normal distribution of data, the mean score of sexual function will be compared between the groups using a repeated measurements ANOVA. If statistical analysis leads to significant results, the post-hoc test will be used to determine the differences between the groups. Comparison of demographic and fertility characteristics of the women will be carried out using statistical tests such as chi-squares and *t*-tests. A significance level of $p < .05$ will be used for statistical analyses.

Discussion: If vitamin D vaginal suppositories improve sexual function among premenopausal women with long-term effects and minimum side effects, the suppositories will be considered a safe complementary and alternative choice for alleviating sexual dysfunction among this group.

Trial registration: IRCT20180704040346N1 at 2018-10-13 prospectively registered.

Keywords: Menopause, Sexual function, Vitamin D vaginal suppository

* Correspondence: z.alimoradi@qums.ac.ir; zainabalimoradi.sbmu.ac.ir@gmail.com
[2]Social Determinants of Health Research Center, Research Institute for Prevention of Non-Communicable Diseases, Qazvin University of Medical Sciences, Bahonar blv., Qazvin 34197-59811, Iran
Full list of author information is available at the end of the article