ISRCTN33082642 https://doi.org/10.1186/ISRCTN33082642

Comparative study of vitamin D vaginal suppository and oral administration on vaginal symptoms in women with breast cancer

Submission date
17/01/2024

Recruitment status
No longer recruiting

Registration date
18/01/2024

Overall study status
Completed

Last Edited
06/03/2025

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
A breast cancer survivor treated with aromatase inhibitor or antiestrogen to prevent recurrent disease often has a higher likelihood of experiencing genitourinary symptoms than the normal population. Current treatment options include the use of low-dose vaginal estrogen, which has data suggesting minimal systemic absorption. However, there is an effort to explore non-hormonal treatments. It has been observed that vitamin D, which has receptors in the vaginal canal, plays a role in epithelial proliferation and can reduce symptoms of genitourinary syndrome of menopause (GSM) by enhancing superficial cell growth. This study compares the effectiveness of oral administration of vitamin D versus vaginal suppositories as a treatment option in a group of breast cancer survivors with GSM symptoms.

Who can participate?
Female breast cancer survivors aged between 20 and 80 years old who are menopausal and have bothersome vaginal symptoms

What does the study involve?
To compare the effectiveness of oral administration of vitamin D versus vaginal suppositories as a treatment option in a group of breast cancer survivors with GSM symptoms, a study was conducted on breast cancer survivors receiving care at Srinagarind Hospital, Thailand. Participants will be monitored for 12 weeks by the primary researcher.

What are the possible benefits and risks of participating?
The benefits that participants will receive include receiving the treatment option of a vitamin D suppository for treating GSM symptoms and benefiting from the per-vaginal examinations of VMI, VHI, and vaginal pH, which can screen for gynecologic disease and cervical cancer simultaneously. The potential risks of treatment include vitamin D and calcium intoxication and vitamin D allergy. The researcher has a protocol for monitoring these conditions through interviews and side effect assessments one week after taking the medication, approved by the ethics committee.

Where is the study run from?
Khon Kaen University (Thailand)

When is the study starting and how long is it expected to run for?
May 2023 to April 2024

Who is funding the study?
1. Investigator initiated and funded
2. Khon Kaen University (Thailand)

Who is the main contact?
Miss. Suppakan Preetikul, MD, suppakanpreetikul@gmail.com.

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Miss Suppakan Preetikul

Contact details
Faculty of Medicine Khon Kaen University
Khon Kaen
Thailand
40000
+66 0897160707
suppakanpreetikul@gmail.com

Additional identifiers

Protocol serial number
0707

Study information

Scientific Title
Effects of vaginal VS oral administration of Vitamin D on vulvovaginal symptoms in breast cancer survivors: a randomized clinical trial

Study objectives
There is no significant difference in the effectiveness of Vitamin D vaginal suppositories compared to oral administration in addressing vaginal symptoms among postmenopausal women with breast cancer undergoing treatment with aromatase inhibitors or GnRH agonists.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 30/05/2023, Center for Ethics in Human Research, Khon Kaen University, Faculty of Medicine (17th floor, Sor Vor 1 building, Mittraphap road, Nai Muang Subdistrict, Muang District, Khon Kaen, 40002, Thailand; +66 043-366621-3; eckku@kku.ac.th), ref: HE661059

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied
Vitamin D treatment for genitourinary syndrome of menopause (GSM) symptoms in postmenopausal women with breast cancer

Interventions
Postmenopausal women, aged 20-80 years old, diagnosed with breast cancer and treated with aromatase inhibitors or GnRH agonists for more than 12 weeks, who present with bothersome vaginal symptoms (defined as the Visual Analog Scores >= 4 scores by interview) and vitamin D insufficiency (defined as the serum total vitamin D < 30 ng/ml) will be recruited. Eligible participants are randomized into two groups. Randomly generated treatment allocations are placed within sealed opaque envelopes. Once a patient has consented to enter a trial an envelope is opened and the patient is then offered the allocated treatment regimen. The control group will receive vaginal vitamin D suppositories while the intervention group are administrated vitamin D orally. Each group are given vitamin D 0.25 mcg daily for 12 weeks.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Calcitriol

Primary outcome(s)
Bothersome vaginal symptoms of GSM measured using a visual analog scale (VAS) at baseline, 6, and 12 weeks

Key secondary outcome(s)
The following secondary outcome measures are assessed at baseline and 12 weeks:
1. Vaginal health index (VHI) measured using a vaginal health index (VHI) score
2. Vaginal Maturation Index measured using a vaginal maturation index (VMI) score
3. Vaginal pH measured using pH paper
4. Serum vitamin D level measured using blood specimen analyzed by electrochemiluminescence binding assay

Completion date

20/04/2024

Eligibility

Key inclusion criteria
1. Breast cancer
2. Treated with aromatase inhibitors or GnRH agonists for longer than 12 weeks
3. Aged 20-80 years old
4. Menopause (defined as no menstruation in the past 12 months)
5. Presented with most bothersome vaginal symptoms (defined as the visual analog scores >= 4 scores by interview)
6. Serum total vitamin D < 30 ng/ml
7. Willing to participate with signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
20 Years

Upper age limit
80 Years

Sex
Female

Total final enrolment
76

Key exclusion criteria
1. History of hormonal use or vitamin D supplement within 12 weeks
2. Recurrent breast cancer
3. History of procedure or vaginal product use within 12 weeks
4. History of vulvovaginal infection within 12 weeks
5. History of abnormal PAP smear
6. History of vitamin D allergy
7. History of intestinal disease
8. Active hepatic disease
9. Impair renal function (GFR < 60 ml/min/1.73m2)
10. Refused to participate

Date of first enrolment
01/06/2023

Date of final enrolment
30/01/2024

Locations

Countries of recruitment
Thailand

Study participating centre
Srinagarind Hospital
Khon Kaen University
Mittraphap road, Nai Muang Subdistrict, Muang District
Khon Kaen
Thailand
40000

Sponsor information

Organisation
Khon Kaen University

ROR
https://ror.org/03cq4gr50

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
Khon Kaen University

Alternative Name(s)
Khon Kaen University in Thailand, , KKU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Thailand

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Ms Suppakan Preetikul at suppakanpreetikul@gmail.com. Clinical data related to baseline characteristics and primary/secondary outcomes will be shared from around August 2024. Informed consent documents were obtained from participants who requested interviews, blood draws, and per-vaginal examinations, approved by the ethics committee. The information provided cannot disclose the identity of the patients. Privacy protection is in place, and patient identity cannot be disclosed.

IPD sharing plan summary
Stored in non-publicly available repository