Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

A comparative study on the effect of Matricaria chamomilla and danazol on mastalgia in women of reproductive age

Protocol summary

Study aim
Determination of the effectiveness of Chamomile extract on the improvement of mastalgia in women of reproductive age.

Design
A double-blind clinical trial study on 100 women of reproductive age in two groups of intervention and control, randomly coded with card selection and treated in parallel.

Settings and conduct
This study will be done on 100 women in reproductive age who refer to gynecology clinic. By simple randomization method patients will be placed in 2 groups by selecting a encoded card. Patients and researcher won't be aware of the kind of medication each group will recieve. Patients will be observed 4 and 6 weeks later after treatment in terms of pain severity, complications and count of times danazole capsule has been used.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women in reproductive age; Women with mastalgia score equal to or greater than four on the visual analog scale; Women whose pain lasts more than 5 days each month; The clinical examination and mammography performed in the patient are normal; The patient does not have a known history of breast disease or malignancy; The patient does not have pulmonary, cardiovascular and costochondritis disease; The patient has no family history of breast cancer; The patient has no history of breast mass or secretion of the breast.
Exclusion criteria: Women with physical and psychological illness; Obese women (Body mass index equal to or greater than 35); Women who are continuously taking medication; Women who have undergone hormone therapy in the last three months.

Intervention groups
Intervention and control groups include chamomile and placebo recipients.

Main outcome variables
Visual analog scale score, Complications of treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171030037093N5**
Registration date: **2019-03-29, 1398/01/09**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-29, 1398/01/09**
Update count: **0**

Registration date
2019-03-29, 1398/01/09

Registrant information

Name
Sadra Ansaripour

Name of organization / entity
Shahrekord University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 31 3650 3487

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st_ansari.s@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-01, 1397/08/10

Expected recruitment end date
2019-06-05, 1398/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study on the effect of Matricaria chamomilla and danazol on mastalgia in women of reproductive age

Public title
Comparison of the effect of chamomile with danazol on women's mastalgia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy women of Reproductive age Women with mastalgia score equal to or greater than four on the visual analog scale Women whose pain lasts more than 5 days each month. Clinical examination and mammography performed in the patient are normal. Patient does not have a known history of breast disease or malignancy. Patient does not have pulmonary, cardiovascular and costochondritis disease. Patient has no family history of breast cancer. Patient has no history of breast mass or secretion of the breast. Patient has satisfiction for participation in the study and has signed the consent form.

Exclusion criteria:
Women with physical and mental illness. Obese patients (Body mass index equal to or greater than 35) Women who are continuously taking medication. Women who have undergone hormone therapy in the last three months.

Age
From **15 years** old to **49 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
For both of intervention groups a code is considered. Patients without prior notice by selecting a code are assorted in one of 2 groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to blinding for each treatment group a code will be selected by the pharmacist. Patients and researcher won't be aware of that untill the end of the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences

Street address
Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713492

Approval date
2018-11-04, 1397/08/13

Ethics committee reference number
IR.SKUMS.REC.1397.211

Health conditions studied

1

Description of health condition studied
Mastalgia

ICD-10 code
N64.4

ICD-10 code description
Mastodynia

Primary outcomes

1

Description
Mastalgia score

Timepoint
Before the intervention begins, 4 and 8 weeks after the intervention begins

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients use chamomile capsule made by barij essence company 250 mg 3 times a day. Also if there was more need to pain relief they use 100 mg danazole capsule up to every 12 hours.

Category
Treatment - Drugs

2

Description
Control group: patients use placebo capsule which is similar to chamomile capsule and is formulated and made by barij essence company as 1 capsule every 8 hours and if there was more need to pain relief they use 100 mg danazole capsule up to every 12 hours.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Clinic
Full name of responsible person
Niloofar Safaei
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Shariati Blvd., Imam Ali Clinic
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2

Recruitment center
Name of recruitment center
Hazrat Rasool clinic
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr. seyed Kamal Solati(Associate Professor of Psychology)
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Rasool Rahimi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
General Surgery
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Person responsible for updating data

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niloo_safaei@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Information on the main outcome can be shared.
When the data will become available and for how long
Start the access period 4 months after printing the results
To whom data/document is available
Researchers working in academia and academia
Under which criteria data/document could be used
Use data to complete basic and applied studies
From where data/document is obtainable
Shahrekord's Kashani Hospital, rahimi.r@skums.ac.ir
What processes are involved for a request to access data/document
Investigating the request of the researcher and providing sufficient documentation of his research and the reason for the use of data can be provided.
Comments