

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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 receive. 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)

Phone

+98 31 3650 3487

Email address

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 satisfaction 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 until 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

Niloofer Safaei

Street address

Shariati Blvd., Imam Ali Clinic

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816788640

Phone

+98 38 3224 2696

Email

niloo_safaei@yahoo.com

2

Recruitment center

Name of recruitment center

Hazrat Rasool clinic

Full name of responsible person

Niloofer Safaei

Street address

Molavi Street., Hazrat Rasool Clinic

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816788640

Phone

+98 38 3226 4833

Email

niloo_safaei@yahoo.com

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)

Street address

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

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 3334 2414

Email

niloo_safaei@yahoo.com

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

Street address

Shahrekord University of Medical Sciences, Building No. 2, University headquarters, Ayatollah Kashani Blvd

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 3334 2414

Fax

Email
rahimi.r@skums.ac.ir
Web page address

Person responsible for scientific 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

Street address
Shahrekord University of Medical Sciences, Building
No. 2, University headquarters, Ayatollah Kashani
Blvd

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713471

Phone
+98 38 3227 4004

Email
rahimi.r@skums.ac.ir

Person responsible for updating data

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

Street address
Shahrekord University of Medical Sciences, Building

No. 2, University headquarters, Ayatollah Kashani
Blvd

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713471

Phone
+98 38 3227 4004

Email
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