

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparative study on the effect of Matricaria Chamomile capsule and Achillea Millefolium capsule on primary dysmenorrhea intensity in university students.

Protocol summary

Study aim

Comparison of the effect of Matricaria Chamomile capsule and Achillea Millefolium capsule on primary dysmenorrhea intensity in university students.

Design

This is a randomized, parallel double blinded clinical trial in the third phase of the study, which will be conducted on 60 university students and its results will be measured.

Settings and conduct

The Research community is university students of Kurdistan Medical Sciences Dormitories. Initially, one month before giving the medications, the demographic and menstrual characteristics of the participants were assessed with a questionnaire and Visual Analog Scale; then they are randomly divided into two equal groups using the envelope A and B containing the capsule of chamomile and capsule of the Achillea Millefolium. participants and researcher do not know the nature of drugs, The researcher evaluate the out comes in the first three days of one month and two month of menstruation after taking capsules.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Single; Starting a menstrual period at the age of 11 to 17; Having a score of 4 to 10 for menstrual pain according to Visual Analogue Scale
Exclusion criteria: Abnormal uterine bleeding during the study; Epilepsy; Coagulation disorder; Allergic Asthma; Pelvic tumor; History of mental illness; consume benzodiazepines; Barbiturats; Narcotics; Anticoagulant; Theophylline; Hormonal drugs in the past three months.

Intervention groups

Matricaria Chamomile consumer group: consume Chamomile capsules 250 mg every 8 hours during the first three days of their menstrual two consecutive cycles. Achillea Millefolium consumer group: consume Achillea Millefolium capsules 150 mg every 8 hours

during the first three days of their menstrual two consecutive cycles.

Main outcome variables

Primary dysmenorrhea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171225038058N1**

Registration date: **2018-03-09, 1396/12/18**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-09, 1396/12/18**

Update count: **0**

Registration date

2018-03-09, 1396/12/18

Registrant information

Name

shiva radfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4331 4753

Email address

shiva.radfar@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-21, 1397/02/31

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

2018-01-20, 1396/10/30
Actual recruitment end date
2018-04-20, 1397/01/31
Trial completion date
empty

Scientific title
Comparative study on the effect of Matricaria CHamomile capsule and Achillea Millefolium capsule on primary dysmenorrhea intensity in university students.

Public title
Compare the effect of Matricaria CHamomile capsule and Achillea Millefolium capsule on menestural pain.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Be single Their menstruation start at the age of 11 to 17
Regular menstrual cycles every 21-35 days A score of 4 to 10 for menstrual pain according to the visual analogue scale
Volunteered to participate in the study
Exclusion criteria:
Have Abnormal bleeding Have history of any Herbal allergy Have Epilepsy Have Coagulation disorder Have Allergic asthma Have Digestive diseases Have Liver disease Have Renal disease Have Ovarian cyst Have Myoma Have pelvic tumor Have Endometriosis Consume Benzodiazepines Consume Barbiturates Consume Narcotics Consume Tricyclic antidepressants Consume Anticoagulants Consume Theophylline Consume Steroid hormones drugs Oral contraceptive pills in the last three months were consumed Consume Alcohol Known Mental illness Have Pelvic inflammatory disease

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Initially one month before taking CHamomile capsule and Achillea Millefolium capsule, demographic and menstrual characteristic questionnaire and the visual Analog Scale will be given to eligible university students and asked them to complete it, in the first three days of menstrual cycle before taking medications. Then envelopes containing 250 mg Matricaria CHamomile capsule or capsule containing 150 mg hydro alcoholic extract of Achillea Millefolium made by Kermanshah College of Pharmacy and named as code A or code B is distributed among participants by colleague researcher. Each code represents the existence of one of a variety of capsules inside the envelope and the researcher does not know

which of the participants will use the envelope A or the envelope B. Only the pharmacist knows the nature of envelopes contain capsules. researcher, her colleague and participants are unaware of of the type of capsules.

Blinding (investigator's opinion)
Double blinded

Blinding description
By sealing a sealed envelope; individuals may randomly build a Kermanshah Pharmacy School in the capsule group of 250 mg of Matricaria CHamomile, Kermanshah Pharmacy Department or in the group of Achillea Millefolium hydro-alcoholic capsules of Kermanshah, Color, size and aroma are quite similar and will be provided by the research collaborator. Apart from the pharmacist, the investigator or the participants will not know the nature of the medications.

Placebo
Not used

Assignment
Parallel

Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

Street address

Kurdistan University of Medical Sciences; Pasdaran Blov

City

sanandaj

Province

Kurdistan

Postal code

6617713446

Approval date

2018-02-19, 1396/11/30

Ethics committee reference number

IR.MUK.REC.1396.326

Health conditions studied

1

Description of health condition studied

Primary dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhea

Primary outcomes

1

Description

Primary dysmenorrhea intensity

Timepoint

Before intervention, 1, 2, 4, 6 hours after intervention.

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

The amount of menstrual bleeding

Timepoint

Before intervention and at the end of the third day of the first cycle and the second cycle of menstruation, after taking the Matricaria Chamomile capsule and Achillea Millefolium capsule

Method of measurement

Pictorial blood assessment chart

2

Description

Side effects of taking the Matricaria Chamomile capsule and Achillea Millefolium capsule

Timepoint

At the end of the third day of the first cycle and the second cycle of menstruation, after taking the Matricaria Chamomile capsule and Achillea Millefolium capsule.

Method of measurement

Questionnaire

3

Description

The number of menstruation days

Timepoint

Before intervention and at the end of the second menstrual cycle after intervention

Method of measurement

The questionnaire based on the number of menstrual days

4

Description

Side effects of taking the Matricaria Chamomile capsule and Achillea Millefolium capsule

Timepoint

At the end of the second menstrual cycle after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

intervention group: Oral capsule 150 mg of Achillea Millefolium (constructed at Kermanshah Pharmacy Faculty) is taken every 8 hours after meal during the first 3 days of menstruation in the first and second cycles of their menstruation.

Category

Treatment - Drugs

2

Description

Control group: Oral capsule 250 mg of Matricaria Chamomile (constructed at Kermanshah Pharmacy Faculty) is taken every 8 hours after meal during the first 3 days of menstruation in their first and second cycle of menstruation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kurdistan University of Medical Sciences

Full name of responsible person

Azad Zand salimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Kurdistan 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

Kurdistan University of Medical Sciences

Full name of responsible person

Shiva Radfar

Position

دانشجوی کارشناسی ارشد مامائی

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

University faculty

Latest degree

Master

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available