

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison Efficacy of hydroalcoholic extract of combined potions of 5 plants of Matricaria Chamomile, Cinnamon zeylanicum, Foeniculum vulgare, Cuminum cyminum and with Mefenamic acid in treatment of moderate to severe Dysmenorrhea in 15-45 year old women

Protocol summary

Study aim

Comparing effect of hydroalcoholic extract of combined plants of Matricaria Matricaria chamomile, Cinnamon zeylanicum, Foeniculum vulgare, Cuminum cyminum and Zataria multiflora with Mefenamic acid in treatment of moderate and severe Dysmenorrhea

Design

In this non blinded randomized parallel clinical trial, 80 Patients are allocated randomly with simple sequential allocation in one of the two groups (herbal extract or mefenamic) and receive the intervention of that group.

Settings and conduct

Women aged 15-45 years old referring to Shahid Mofateh clinic of Yasuj suffering from severe dysmenorrhea allocated in one of two groups. the first group will received combined extract of 5 herbs provided in form of capsule ,then 2 day before onset of menstrual cycle till 3 days after one capsule prescribed with for two consecutive cycle. In second group mefenamic capsule 250 mg is prescribed every 8 hour same as first group. pain severity of patients(by Visual analogue scale (VAS) and changes in time and volume of menstrual bleeding will be checked and recorded by questionnaire during treatment and two weeks after that .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 15-45 years old with moderate to severe Dysmenorrhea, having informed consent form Exclusion criteria: Patients with coagulation disorders, vaginal infection, pregnant women and those with a history of herbal or medicinal allergy.

Intervention groups

Combined extract of 5 herbs provided in form of capsule, then 2 day before menstrual cycle till 3 days after every 12 hours one capsule prescribed after meal with one glass of water for two sequential cycle. In control group 250 mg mefenamic capsule is prescribed every 8 hour

same as first group.

Main outcome variables

Severity of pain according to Visual analogue scales (VAS) and change in menstrual cycle by questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081011001323N24**

Registration date: **2019-12-10, 1398/09/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-10, 1398/09/19**

Update count: **0**

Registration date

2019-12-10, 1398/09/19

Registrant information

Name

Sadrollah Mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3334 6070

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-01, 1398/08/10

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Efficacy of hydroalcoholic extract of combined potions of 5 plants of Matricaria Chamomile, Cinnamon zeylanicum, Foeniculum vulgare, Cuminum cyminum and with Mefenamic acid in treatment of moderate to severe Dysmenorrhea in 15-45 year old women

Public title

effect of combined extract of Matricaria Chamomile, Cinnamon zeylanicum, Foeniculum vulgare, Cuminum cyminum and Zataria multiflora in treatment of Dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Childbearing women of 15-45 years old Suffering from moderate to severe Dysmenorrhea Having informed consent form to enter the study

Exclusion criteria:

Presence of vaginal infection Presence of pelvic inflammation Presence of benign or malignant pelvic tumor Coagulopathy Pregnancy Allergy to medical or herbal drugs Suffering from cardiopulmonary disease Suffering from renal or hepatic disorder

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are allocated randomly with simple random allocation method by use of random number table to one of each group combined herbal extract or mefenamic acid) and received the intervention of that group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj University of Medical Sciences

Street address

Yasuj University of Medical Sciences, Mottahari srteet, Yasuj, Iran

City

Yasuj

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Kohgilouyeh-va-Boyerahmad

Postal code

7591741414

Approval date

2019-10-26, 1398/08/04

Ethics committee reference number

IR.YUMS.REC.1398.113

Health conditions studied

1

Description of health condition studied

Treatment of primary dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhea

Primary outcomes

1

Description

Pain intensity in dysmenorrhea

Timepoint

Before and during first 5 day of menstrual cycle in two consecutive cycle

Method of measurement

Visual Analogue Scale(VAS)

Secondary outcomes

1

Description

Changes in time and volume of menstrual bleeding

Timepoint

During treatment and two weeks after in two consecutive menstrual cycle

Method of measurement

By questionnaire and reports of patients

Intervention groups

1

Description

Intervention group: Combined extract of 5 herbs provided in form of capsule ,then 2 day before onset of menstrual cycle till 3 days after every 12 hours one capsule prescribed with one glass of water for two consecutive cycle.

Category

Treatment - Drugs

2

Description

Control group: Mefenamic capsule 250 mg is prescribed every 12 hour with one glass of water 2 day before onset of menstrual cycle till 3 days after it for two consecutive cycle.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mofateh clinic of Yasuj

Full name of responsible person

Sadrolleh Mehrabi

Street address

Shahid Mofateh clinic, Montazeri street,Yasuj,Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Ali Mousavizadeh

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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

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Sadrollah Mehrabi

Position

Professor, Chairman of Urology Department, Yasuj University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Other areas of specialty/work

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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

There is no further 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