Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of Comparing the effect of Achillea Millefolium capsules and Mefenamic Acid on the amount and duration of menstrual bleeding in women affected by menorrhagia

Protocol summary

Summary

This study is conducted to determine the effect of Achillea Millefolium capsule on menorrhagia. In this clinical trial, 90 women with complaint of heavy menstrual bleeding were selected and after a control cycle for evaluating the primary bleeding volume, were randomly allocated to Achillea Millefolium or control groups. Inclusion criteria: Affected by menorrhagia, No history of known systemic or pelvic inflammatory diseases, Not pregnant, No consumption of specific medications,No abnormal pap smear or ultrasonography, No history of sensitivity to medicinal plants. Exclusion criteria: sensitivity to the study medications, Failure to adhere to prescribed treatment, , Unwilling to continue participation in the study,Tacking any herbal or chemical drug during the study. Both groups were subjected to mefenamic acid capsule with 500 mg every 8 hours,from the first day to the end of bleeding,up to seven days, for two consecutive cycles.In Achillea Millefolium group, , in addition to mefenamic acid, Achillea Millefolium capsules, two capsules every 12 hours per day,from the first day to the end of bleeding,up to seven days , were prescribed.In control group, instead of Achillea Millefolium capsules,placebo of Achillea Millefolium was prescribed with the same order. Data on the amount and duration of bleeding were checked and compared before and after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016073029126N1**
Registration date: **2017-07-30, 1396/05/08**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-30, 1396/05/08

Registrant information

Name

Pegah matoury

Name of organization / entity

medical science of tehran

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of Comparing the effect of Achillea Millefolium capsules and Mefenamic Acid on the amount and duration of menstrual bleeding in women affected by menorrhagia

Public title

The effect of Achillea Millefolium on heavy menstrual bleeding

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Affected by menorrhagia, Regular menstrual cycles,Body mass index between18.5-29.5,Age between 18-45 years,No history of known systemic or pelvic inflammatory diseases, Not pregnant, No consumption of specific medications,No abnormal pap smear or ultrasonography, No history of sensitivity to medicinal plants. Exclusion criteria: Pregnancy during the study, Failure to adhere to prescribed treatment, sensitivity to the study medications, Unwilling to continue participation in the study,Occurrence a specific disease,Taking any herbal or chemical drug during the study,Occurrence of a specific event during the study.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

This study has been done by triple blind method. To do this, patients, researcher and statistical consultant were not aware of prescribed drug's nature. 90 women using Excel software, were randomly allocated to Achillea Millefolium or control groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak of University of Medical Sciences

Street address

Beside Amir almomenin hospital, Sardasht St, Basij Sq,Arak

City

Arak

Postal code

Approval date

2015-11-07, 1394/08/16

Ethics committee reference number

IR.ARAKMU.REC.1394.181

Health conditions studied

1

Description of health condition studied

Menorrhagia

ICD-10 code

N92-0

ICD-10 code description

excessive and frequent menturation with regular cycle

Primary outcomes

1

Description

Amount of bleeding

Timepoint

before treatment، First month during treatment, second month during treatment

Method of measurement

Higam Chart

2

Description

Duration of bleeding

Timepoint

before treatment، First month during treatment, second month during treatment

Method of measurement

Higam Chart

Secondary outcomes

1

Description

Side effects of medication

Timepoint

2 months after treatment

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention 1: In control group, Mefenamic acid capsule 500 mg every 8 hours and placebo capsules 500 mg per day every 12 hours, were prescribed from the first day to the end of bleeding up to seven days.

Category

Placebo

2

Description
Intervention 2: In Achillea Millefolium group, Mefenamic acid capsules, 500 mg every 8 hours and hydro alcoholic extract of Achillea Millefolium capsules, 500 mg per day every 12 hours,were prescribed, from the first day to the end of bleeding up to seven days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Clinic
Full name of responsible person
Street address
Masjed Seyedha Av, Emam St, Arak
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Arak University of Medical Sciences
Full name of responsible person
Ali Ghazaavi
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Beside Amir almomenin hospital, Sardasht St, Basij Sq, Arak
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Full name of responsible person
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty