

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigation the effects of hydro alcoholic extract capsule of *Achillea Millefolium* on the Menorrhagia of women referred to the health center of Tehran University of medical science in 2015

Protocol summary

Summary

The aim of this study is to specify the effect of hydro alcoholic extract capsule of *Achillea Millefolium* on the Menorrhagia of the women referred to the health center of Tehran University of medical science. The study conducted in 2015 and it was based on the triple blind randomized controlled clinical trial. In this clinical trial, 126 women with complaint of menorrhagia were selected. Inclusion criteria: body mass index between 18.5-29.9; affected by menorrhagia; age between 18-45 years old; no history of known systemic or pelvic inflammatory diseases; no pregnancy; 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. Women categorized into the control and intervention groups. Both groups consumed 500 mg Mefenamic acid capsule every 8 hours, from the first day to the end of bleeding, for two consecutive cycles. The intervention group consumed one *Achillea Millefolium* capsule every 8 hours. However, the controlled groups consumed placebo instead of *Achillea Millefolium* capsule. Data on the amount and duration of bleeding (using Higam chart) were checked and compared before, duration and after treatment using SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041627417N1**
Registration date: **2016-05-03, 1395/02/14**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-03, 1395/02/14

Registrant information

Name

Farzaneh Ebrahimi Varzaneh

Name of organization / entity

Shahid Beheshti University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 21 23871

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effects of hydro alcoholic extract capsule of *Achillea Millefolium* on the Menorrhagia of women referred to the health center of Tehran University of medical science in 2015

Public title

The effects of Achillea Millefolium on the heavy menstrual bleeding

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Body mass index between 18.5-29.9; affected by menorrhagia; age between 18-45 years old; no history of known systemic or pelvic inflammatory diseases; no pregnancy; 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; taking any herbal or chemical drug during the study.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti of University of Medical Sciences

Street address

Beside Taleghani hospital, Shahid Arabi St., Yaman St., Shahid Chamran Highway, Tehran

City

Tehran

Postal code

1985717443

Approval date

2015-11-03, 1394/08/12

Ethics committee reference number

SBMU2.REC.1349.136.

Health conditions studied**1****Description of health condition studied**

Menorrhagia

ICD-10 code

N92-0

ICD-10 code description

Excessive and frequent menstruation with regular cycle

Primary outcomes**1****Description**

Amount of bleeding

Timepoint

Before treatment, first month during treatment, second month during treatment and one month after the end of treatment

Method of measurement

Higam Chart

Secondary outcomes**1****Description**

Duration of bleeding

Timepoint

Before treatment, first month during treatment, second month during treatment and one month after the end of treatment

Method of measurement

Higam Chart

Intervention groups**1****Description**

In intervention group, Mefenamic acid capsules, 500 mg every 8 hours and hydro alcoholic extract of Achillea Millefolium capsules, 150 mg per day, every 8 hours, were prescribed, from the first day to the end of bleeding.

Category

Treatment - Drugs

2**Description**

In control group, Mefenamic acid capsule 500 mg every 8 hours and placebo capsules 150 mg per day, every 8 hours, were prescribed from the first day to the end of bleeding.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers affiliated to Tehran University of medical science

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Beside Taleghani Hospital, Shahid Arabi St., Yaman St., Shahid Chamran Highway, Tehran

City

Tehran

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 Shahid Beheshti 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

Name of organization / entity

School of Nursing and Midwifery, Shahid Beheshti

Full name of responsible person

Fatemeh Nahidi

Position

Reproductive Health PhD

Other areas of specialty/work

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Person responsible for scientific inquiries

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MSc student of midwifery

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Person responsible for updating data

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Position

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Other areas of specialty/work

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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