

# 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

###### Email address

f.ebrahimi69@sbmu.ac.ir

##### 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; tacking 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**

**Street address**

In Front of Shahid Rajaei Hospital, Niyayesh, Valiasr St., Tehran

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

School of Nursing and Midwifery of Shahid Beheshti

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Farzanehi Ebrahimi Varzaneh

**Position**

MSc student of midwifery

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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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*