

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The Effect of Hypericum perforatum on early menopausal symptoms

#### Protocol summary

##### Summary

The present study aims to analyze the effect of Hypericum perforatum or as is called perforate on early complications of menopause. The study is a double blind clinical trial conducted on 80 women from Izeh city. The simple purposive sampling is used. (medicine and placebo groups). The subjects received Perforan tablet containing 330 micro grams Hypericin or placebo three time a day for 2 months. Data were collected using interview, personal characteristic questionnaire and Kupperman index symptom questionnaire in two rounds before treatment and 4 times after treatment. The study's criteria include age between 45 and 60, amenorrhoea for at least 12 months, having at least two of menopause symptoms based on Kupperman index, and the ability to read and write. Women over the age 30 with unnatural menopause or hysterectomy amenorrhoea, oophorectomy, and radiation therapy due to systematic disease were excluded from the study. Hypericum perforatum is the independent variable while the dependent variables include: hot flush, night sweats, insomnia, anger, depression, tiredness, headache, frequent urination, and pain in the bladder. Moreover, the intervening variables include age, education, marital status, length of time spent from amenorrhea, and body mass index.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016040820053N2**  
Registration date: **2016-09-19, 1395/06/29**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-09-19, 1395/06/29

#### Registrant information

##### Name

Narges Majidipour

##### Name of organization / entity

Dezful University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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#### Recruitment status

##### Recruitment complete

#### Funding source

University of Medical Sciences Jundishapur Ahvaz, Vice  
Chancellor Of Research

#### Expected recruitment start date

2009-06-15, 1388/03/25

#### Expected recruitment end date

2010-11-15, 1389/08/24

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The Effect of Hypericum perforatum on early menopausal  
symptoms

#### Public title

The Effect of Hypericum perforatum on early menopausal  
symptoms

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Age45-60 years, amenorrhea for at least 12 months, at  
least two symptoms of menopause, according to  
Kupperman index, patients could read and write;  
abnormal menopause induced ex. hysterectomy,

oophorectomy or radiation therapy for known systemic disease such as endocrine disorders (thyrotoxicosis), dietary intake of phyto estrogen and specific regimes , having physical and mental diseases, sexual hormones consumption , sensitivity to herbal drugs, athletes women, antidepressants consumption, herbal medicines consumption, body mass index higher than 30 were excluded.

#### **Age**

From **45 years** old to **60 years** old

#### **Gender**

Female

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **80**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double 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 the Ahvaz Jondishapour  
University of Medical Sciences

###### **Street address**

Golestan Bolvar

###### **City**

Ahvaz

###### **Postal code**

6135715794

##### **Approval date**

2009-10-01, 1388/07/09

##### **Ethics committee reference number**

U-88221

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

menopausal symptoms

##### **ICD-10 code**

N95.1

### **ICD-10 code description**

Menopausal and female climacteric states

### **Primary outcomes**

#### **1**

##### **Description**

Hot flushes

##### **Timepoint**

Before the study and weeks 2, 4, 6 and 8

##### **Method of measurement**

Kupperman's index

#### **2**

##### **Description**

Depression

##### **Timepoint**

Before the study and weeks 2, 4, 6 and 8

##### **Method of measurement**

Kupperman's index

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

For 2 months Perforan pills contain 330 µg hypericum  
tree times a day

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

For 2 months Placebo pills 3 times a day

##### **Category**

Treatment - Drugs

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Ahvaz Jundishapur University of Medical Sciences ,  
Vice Chancellor Of Research

###### **Full name of responsible person**

###### **Street address**

###### **City**

Ahvaz

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

**Name of organization / entity**

Jundishapur Ahvaz University of Medical Sciences,  
Vice Chancellor Of Research

**Full name of responsible person**

Shahnaz najar

**Street address**

Golestan Blvd.

**City**

Ahvaz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Jundishapur Ahvaz University of Medical Sciences, Vice  
Chancellor Of Research

**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**

Ahvaz Jondishapour university of medical sciences

**Full name of responsible person**

Alieh Etemadi Kermani

**Position**

Master of Midwifery

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**Web page address****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*