

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Study the effect of different doses of piascledine on hot flashing of menopausal women in Jahrom city.

Protocol summary

Summary

The aim of this proposal is to study the effect of different doses of piascledine on hot flashing of menopausal women in Jahrom city. sampling is easy with random assignment to experimental and control groups. women with menopausal according to kuperman index will be participated in the study. control group do not getting placebo. Inclusion criteria: menopausal women that have not menstrual cycle among last one year; having hotflashes according to kuperman index; do not take another treatment such as hormone replacement, food supplements and plantal drugs. Exclusion criteria: women can not continue using drug beacuse of gastrointestinal complication or other things. The total sample size is 69. 23 patients in case group and 23 patients in control group (there are 2 control groups). case group (1) will take one piascledine 300mg once a day, case group (2) will take 2 piascledine 300mg once a day and group 3 is control and will not take anything. the duration of taking drug is 3 months. finally the changes of hotflashing will be study according to kuperman index. the study is three blind (patients in study, analysers and comittee).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051821653N3**

Registration date: **2015-06-15, 1394/03/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-15, 1394/03/25

Registrant information

Name

Athar Rasekh Jahromi

Name of organization / entity

Jahrom University of Medical Sciences

Country

Iran (Islamic Republic of)

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a.rasekh@jums.ac.ir

Recruitment status

Recruitment complete

Funding source

Jahrom University of Medical Science

Expected recruitment start date

2015-03-21, 1394/01/01

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

Study the effect of different doses of piascledine on hot flashing of menopausal women in Jahrom city.

Public title

Evaluation of treatment in menopausal wemon with hotflashes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: menopausal women that have not menstrual cycle among last one year; having hotflashes according to kuperman index; do not take another treatment such as hormone replacement, food supplements and plantal drugs. Exclusion criteria:

nonmenopausal women; do not have hotflashing according to kuperman index; taking hormone replacement therapy; women can not continue using drug beacuse of gastrointestinal complication or other things.

Age

No age limit

Gender

Female

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: 69

Randomization (investigator's opinion)

Randomized

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

Triple blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Jahrom University of Medical Science

Street address

Motahhari street, Jahrom, Fars

City

Jahrom

Postal code**Approval date**

2015-02-25, 1393/12/06

Ethics committee reference number

Jums.REC.1393.121

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

menopausal

ICD-10 code

N95

ICD-10 code description

Menopausal and other perimenopausal disorders

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

Hotflashes

Timepoint

Before intervention and in first, second and third month after intervention

Method of measurement

Scoring is from 0 to 3 according to: not at all (0), a little (1), quite a bit (2), Extremely (3). then the hotflashes score will multiply to 4.

2**Description**

Paraesthesia

Timepoint

Before intervention and in first, second and third month after intervention

Method of measurement

Scoring is from 0 to 3 according to: not at all (0), a little (1), quite a bit (2), Extremely (3). then the paraesthesia score will multiply to 2.

3**Description**

linsomnia

Timepoint

Before intervention and in first, second and third month after intervention

Method of measurement

Scoring is from 0 to 3 according to: not at all (0), a little (1), quite a bit (2), Extremely (3). then the insomnia score will multiply to 2.

4**Description**

Nervousness

Timepoint

Before intervention and in first, second and third month after intervention

Method of measurement

Scoring is from 0 to 3 according to: not at all (0), a little (1), quite a bit (2), Extremely (3). then the nervousness score will multiply to 2.

5**Description**

Melancholia

Timepoint

Before intervention and in first, second and third month after intervention

Method of measurement

Scoring is from 0 to 3 according to: not at all (0), a little (1), quite a bit (2), Extremely (3). then the melancholia score will multiply to 1.

6

Description

Vertigo

Timepoint

Before intervention and in first, second and third month after intervention

Method of measurement

Scoring is from 0 to 3 according to: not at all (0), a little (1), quite a bit (2), Extremely (3). then the vertigo score will multiply to 1.

7

Description

Weakness

Timepoint

Before intervention and in first, second and third month after intervention

Method of measurement

Scoring is from 0 to 3 according to: not at all (0), a little (1), quite a bit (2), Extremely (3). then the weakness score will multiply to 1

8

Description

Arthralgia or myalgia

Timepoint

Before intervention and in first, second and third month after intervention

Method of measurement

Scoring is from 0 to 3 according to: not at all (0), a little (1), quite a bit (2), Extremely (3). then the arthralgia or myalgia score will multiply to 1.

9

Description

Headache

Timepoint

Before intervention and in first, second and third month after intervention

Method of measurement

Scoring is from 0 to 3 according to: not at all (0), a little (1), quite a bit (2), Extremely (3). then the headache score will multiply to 1.

10

Description

Palpitations

Timepoint

Before intervention and in first, second and third month after intervention

Method of measurement

Scoring is from 0 to 3 according to: not at all (0), a little (1), quite a bit (2), Extremely (3). then the palpitations score will multiply to 1.

11

Description

Formication

Timepoint

Before intervention and in first, second and third month after intervention

Method of measurement

Scoring is from 0 to 3 according to: not at all (0), a little (1), quite a bit (2), Extremely (3). then the formication score will multiply to 1.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: no intervention will take on them and do not take piascledine.

Category

Treatment - Drugs

2

Description

Case group (number1): will take one piascledine 300 mg pill daily, during three months. piascledine should be used with food and a glass of water.

Category

Treatment - Drugs

3

Description

Case group (number2): will take two piascledine 300 mg pill daily, during three months. piascledine should be used with food and a glass of water.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Doctor Athar Rasekh Jahromi`s clinic

Full name of responsible person

Athar Rasekh Jahromi

Street address

Farmandari Street, Jahrom, Fars

City

Jahrom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Abas Rahmnia
Street address
 Motahari Street, Jahrom, Fars
City
 Jahrom
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Jahrom 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
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Full name of responsible person
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Person responsible for updating data

Contact

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