

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Investigation of the effect of Reepaven drug on severity of pain and bleeding during menstruation in women of childbearing age compared with placebo

Protocol summary

Study aim

Determination of the effect of Reepaven drug on the severity of pain and bleeding during menstruation in women compared to placebo

Design

Clinical trial study with control group, with parallel groups, double-blind, randomized by simple randomization method using random numbers table, 80 patients, phase 3

Settings and conduct

In this study, the samples were selected from women who suffer from painful menstruation or heavy bleeding, using the Convenience Sampling method and individuals were divided into groups by simple randomization. If patients wish to participate in this research, first the goals and method of conducting the study for patients were explained and then, a written consent was obtained from all volunteer patients. In this study, 80 women were randomly assigned to study in two groups of 40 people (the Reepaven group and the placebo group). At the first visit, after recording the severity of pain during menstruation and completing the women's health questionnaire, patients will be asked to take 3 pills (after breakfast, lunch, dinner) during the first two days of menstruation. And in the remaining days, take 2 tablets daily (after lunch and dinner), and at the next visit, the severity of the pain and the women's health questionnaire will be recorded again. In addition, all patients are told that they can use previous drugs and methods that can be used to relieve pain and reduce bleeding if desired, and this combination drug is a complementary treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Painful menstrual bleeding or heavy bleeding; Aged 18-50 years; exclusion Criteria: Pregnancy or lactation; Menopause; Patient's reluctance to cooperate; Not taking the drug during the study

Intervention groups

Reepaven drug group, placebo group

Main outcome variables

Pain intensity; Bleeding intensity; Impact of disease severity on daily activities

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140804018677N4**

Registration date: **2020-06-03, 1399/03/14**

Registration timing: **retrospective**

Last update: **2020-06-03, 1399/03/14**

Update count: **0**

Registration date

2020-06-03, 1399/03/14

Registrant information

Name

soodeh razeghi Jahromi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-04-20, 1398/01/31
Actual recruitment start date
2019-01-21, 1397/11/01
Actual recruitment end date
2019-04-20, 1398/01/31
Trial completion date
2019-05-21, 1398/02/31

Scientific title
Investigation of the effect of Reepaven drug on severity of pain and bleeding during menstruation in women of childbearing age compared with placebo

Public title
Reepaven effect on severity of pain and bleeding during menstruation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Painful menstrual cramps or heavy bleeding Aged 18-50years
Exclusion criteria:
Pregnancy and lactation Menopause Patients' reluctance to participate in the study Not taking the drug during the study period

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, patients were assigned to two groups of Reepaven and placebo based on a Simple randomization method. This means that all participants had an equal chance of being in each group. The first step is to create a random sequence. For this purpose, we used a table of random numbers. From the beginning, it was decided to go down to read the numbers in the table of random numbers, after selecting the starting point. We then determined that even numbers were assigned to the intervention group and individual numbers were assigned to the placebo group. Due to the fact that when using simple randomization methods, especially in low sample size, it is possible that the two groups do not equal at the same time, so if a group reaches its sample size earlier, then we must ignore the relevant figures, and complete the opposite group. One of the project's colleagues put his finger on a point in the table with his eyes closed, and then, as scheduled, moved down and wrote down the numbers until they reached the sample size in both groups. Each number, depending on whether they were even or odd, represented a group to which we assigned code A (intervention) and B (placebo). With this

method, we had a specific sequence of 80 codes A and B at the end, indicating that the first to eightieth person to be included in the study should belong to each group. We wrote the code on a piece of paper in order and put it in an envelope, to use it during sampling. Thus, after reviewing the entry criteria and, if the client wishes, we entered each person into the groups according to our pre-determined list.

Blinding (investigator's opinion)

Not 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 medical university

Street address

No. 46, West Arghavan St., Farahzadi Blv., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2019-01-21, 1397/11/01

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.1173

Health conditions studied

1

Description of health condition studied

Women with painful menstrual cramps or heavy bleeding

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The severity of the pain

Timepoint

baseline and end of study

Method of measurement

Women's Health Questionnaire

2

Description

Bleeding severity

Timepoint

baseline and end of study

Method of measurement

Women's Health Questionnaire

3

Description

The effect of disease severity on daily activity

Timepoint

baseline and end of study

Method of measurement

Women's Health Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Reepaven from Ghaem Darou Company (Persicaria bistorta, Quercus, Saccharum spontaneum and Punica granatum); in the first two days of menstruation, 3 pills a day (after breakfast, lunch and dinner) and on the remaining days of the period, 2 pills daily (after lunch and dinner)

Category

Treatment - Drugs

2

Description

Control group: placebo; in the first two days of menstruation, 3 pills a day (after breakfast, lunch and dinner) and on the remaining days of the period, 2 pills daily (after lunch and dinner)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

private clinic

Full name of responsible person

Soodeh Razeghi Jahromi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Vice Chancellor for Research, Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soodeh Razghei Jahromi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available