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

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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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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
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Other areas of specialty/work
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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