Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparative study of the effect of hypnotherapy and Monstrogol capsule on primary dysmenorrhea

Protocol summary

Study aim

Comparative study of the effect of hypnotherapy and Monstrogol capsule on primary dysmenorrhea in girls living in dormitories of Isfahan University of Medical Science in 2022

Design

The clinical trial has two groups of control and intervention, double-blind, randomized, on 72 patients with 36 people in each group. This randomization will be done by minimization software.

Settings and conduct

People with primary dysmenorrhea are randomly divided into control and intervention groups by minimazaition software. The control group receives the monstrog capsule in the dormitory and the intervention group in the obstetrics clinic, which has been prepared for the research, undergoes hypnotherapy by the researcher. This research is double-blind because the questioner and the analyzer are unaware of the grouping of people and identify people with a code.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Conscious consent to participate in research Single students living in dormitories Suffering age 25-18 years Having regular menstrual periods Having primary dysmenorrhea for at least two previous consecutive periods No application of complementary medicine methods during the last two months

Intervention groups

Hypnotherapy in the intervention group will be performed to evaluate its effectiveness on the severity of primary dysmenorrhea pain, bleeding volume and number of days of pain. Monstrogel capsules in the control group will be evaluated to evaluate its effectiveness on the severity of primary dysmenorrhea pain, bleeding volume and number of days of pain.

Main outcome variables

Pain score, Number of days of pain and Bleeding volume

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220203053922N1**
Registration date: **2022-03-19, 1400/12/28**
Registration timing: **prospective**

Last update: **2022-03-19, 1400/12/28**
Update count: **0**

Registration date

2022-03-19, 1400/12/28

Registrant information

Name

Mina Navabi Zadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4522 2688

Email address

navabi2170@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-06-05, 1401/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of hypnotherapy and Monstrogol capsule on primary dysmenorrhea

Public title

Comparative study of the effect of hypnotherapy and Monstrogol capsule on primary dysmenorrhea in girls living in dormitories of Isfahan University of Medical Science in 2022

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Conscious consent to participate in research Single students living in dormitories Suffering age 25-18 years Having regular menstrual periods Having primary dysmenorrhea for at least two consecutive previous periods No application of complementary medicine methods during the last two months Painful menstruation in most menstrual cycles with a pain score of at least 4 out of 10 according to the Visual Analogue Scale (VAS) during two periodic periods Hypnosis of people

Exclusion criteria:

Any known disease of the genital tract Secondary dysmenorrhea History of abdominal or pelvic surgery Endometriosis Tobacco use (cigarettes, hookah and drugs), alcohol Speech, hearing, and mental problems Heart, kidney, respiratory, diabetes, asthma, hypothyroidism or hyperthyroidism, epilepsy and other patients in need of medication Sudden weight loss Special diet (vegetarian) Do professional exercise and intense physical exercises Use of herbs, traditional and complementary medicine during the last two months Psychological problems and diseases requiring medication (bipolar disorder, psychosis, major depression, obsession, borderline disorders, dependent personality disorder, schizoid personality disorder, paranoid personality disorder) based on self-reported research units Having coagulation disorders and taking anticoagulants Existence of depression in the individual based on the score obtained from the DASS21 questionnaire

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, sample selection and random assignment in two groups using Minimization software will be used; In this way, the list of people is entered into the software by coding and people are randomly selected by the software, and are placed in two groups of test and control.

Blinding (investigator's opinion)

Double blinded

Blinding description

This research will be a double-blind clinical trial (because the analyzer and the questioner will be unaware of which group the people are in) and the collection of information and random allocation of samples using Minimization software, so this study, two Group (test and control group) is three-stage and multivariate. The questioner is not aware of the grouping of individuals when recording information and results, and the analyzer is not aware of the grouping of individuals when analyzing data, and individuals are examined by specific codes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

22 plack, No. 4 West, Narvan st, Shahed blvd

City

Shahin Shahr

Province

Isfehan

Postal code

8319918292

Approval date

2022-01-31, 1400/11/11

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.203

Health conditions studied

1

Description of health condition studied

Primary dysmenorrhea

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score

Timepoint

Before. Immediately and two months after the intervention

Method of measurement

Pain ruler

2

Description

Number of pain days

Timepoint

Before. Immediately and two months after the intervention

Method of measurement

Asking the patient

3

Description

Bleeding volume

Timepoint

Before. Immediately and two months after the intervention

Method of measurement

PBLAC chart

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Hypnotherapy. Hypnotherapy will be performed in three sessions of 20 minutes for the experimental group individually.In the first session, hypnotherapy is introduced as a safe and uncomplicated medical treatment and also indoctrination test is performed. At the end of the first session, a light ecstasy and simple relaxation are given to the subjects.In the second session, various techniques are used to enter the trance, and following the involuntary closing of the eyes, inductions related to muscle relaxation and deepening techniques will be performed, and analgesia will begin. In the hypnosis phase, conditioning is done and they learn how to be able to anesthetize their desired areas. In the third session, trance practice and self-hypnotherapy will be performed and more deepening techniques will be used and people will be conditioned to fall into ecstasy when hearing dysmenorrhea by listening to the researcher's instincts and immediately anesthetize their desired points. After these steps, with the onset of dysmenorrhea, the subjects will be able to enter the trance and begin analgesia by listening to the researcher's hypnotherapy.

Category

Treatment - Other

2

Description

Control group: Menstrog capsule. Monstrogol (dry extract of saffron stigma, anise and celery) is a herbal capsule that has the effect of reducing menstrual pain and has an effect on smooth muscle contraction and has anti-inflammatory properties. This capsule contains 1/4 mg of dry extract powder of saffron stigma, 1/60 mg of dry extract powder of anise fruit and 1/16 mg of dry extract powder of celery. The amount of drug is 2.8-2.2 microliters of total essential oil and 3.1-1 microliters of anethole in each capsule. People in the control group of Monstrogol drug produced by Gol Daroo Company take one capsule every 8 hours for 3 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dormitory of Isfahan University of Medical Sciences

Full name of responsible person

Ms. Maryam Masoudi

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Hezar Jerib st.

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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?

Yes

Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Full name of responsible person
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navabi2170@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Confidentiality of information of the subjects
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is 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
Title and more details about the data/document
Comparative study of the effect of hypnotherapy and Monstrogol capsule on primary dysmenorrhea in girls living in dormitories of Isfahan University of Medical Science in 2022
When the data will become available and for how

long

12 Months

To whom data/document is available

Researcher

Under which criteria data/document could be used

If the subjects agree

From where data/document is obtainable

Researcher

What processes are involved for a request to access data/document

Contact the researcher by phone and email

Comments