

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The Comparison of Mindfulness Based Stress Reduction(MBSR), flaxseed oil (Linum usitatissimum) and auriculotherapy on pain intensity and duration of labor in nulliparous women

Protocol summary

Study aim

The Comparison of Mindfulness Based Stress Reduction(MBSR), flaxseed oil (Linum usitatissimum) and auriculotherapy on pain intensity And duration of labor in nulliparous women

Design

Randomized clinical trial with parallel groups consisting of 4 groups including three intervention groups and one control group.

Settings and conduct

The study will be conducted at Khatam Al-Anbia Hospital and Baft County Health Centers in Kerman province and will be double blind so that patients and statistical analysts won't have any information about the intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Low risk pregnancy; 40-37 weeks gestational age; Cephalic presentation; Single heart pregnancy; at least one healthy ear; one with a healthy water bag; Non-inclusion criteria:Receiving low-dose medications within 3 hours of study initiation and lifetime;Drug addiction; being an athlete; using oxytocin to induce and accelerate childbirth; psychological problem

Intervention groups

Intervention group 1: Uriculotherapy; Intervention group 2: Flaxseed oil use; Intervention group 3: Mindfulness-based stress reduction;Control group: Routine care of labor room.

Main outcome variables

Labor pain intensity; duration of labor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191130045549N1**

Registration date: **2020-02-26, 1398/12/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-26, 1398/12/07**

Update count: **0**

Registration date

2020-02-26, 1398/12/07

Registrant information

Name

Omolbanin Heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4244 1785

Email address

heydari201203@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of Mindfulness Based Stress Reduction(MBSR), flaxseed oil (Linum usitatissimum) and auriculotherapy on pain intensity and duration of labor in

nulliparous women Public title Effect of Mindfulness Based Stress Reduction (MBSR), flaxseed oil (Linum usitatissimum) and auriculotherapy on pain intensity and duration of labor Purpose Supportive Inclusion/Exclusion criteria Inclusion criteria: Inclusion criteria in Auriculotherapy group: Low risk pregnancy Being at 37th-40th week of pregnancy Cephalic presentation Single pregnancy 4cm dilatation and uterine contractions for 30 seconds and 2-3 contractions in 10 minutes Ages between 18-35 years old Body mass index ranged from 19.8 to 26.4 Literacy at least reading and writing abilities At least one healthy ear Having a healthy amniotic sac Inclusion criteria in Flaxseed Oil Group and Mindfulness-Based Stress Reduction Counseling: Age of 18-35 years Single pregnancy 35th week of pregnancy Literacy at least reading and writing abilities Willingness to participate in the study Exclusion criteria: Receiving low-dose medications within 3 hours of study initiation and lifetime Addiction to drugs Being an athlete History of infertility Use of oxytocin to induce and accelerate labor High-risk pregnancy Psychological problem Having trouble communicating Age From 17 years old to 36 years old Gender Female Phase N/A Groups that have been masked <i>No information</i> Sample size Target sample size: 160 Randomization (investigator's opinion) Randomized Randomization description Simple, individual randomization, drawing number method Blinding (investigator's opinion) Not blinded Blinding description Placebo Not used Assignment Parallel Other design features Secondary Ids empty Ethics committees 1 Ethics committee	Name of ethics committee Ethics Committee of Kerman University of Medical Sciences Street address Ghadir 3 Alley 3; Golha 2 township; Baft City Baft Province Kerman Postal code 7856146676 Approval date 2019-11-30, 1398/09/09 Ethics committee reference number IR.KMU.REC.1398.400 Health conditions studied 1 Description of health condition studied Duration of delivery ICD-10 code ICD-10 code description 2 Description of health condition studied intensity of labor pain ICD-10 code ICD-10 code description Primary outcomes 1 Description Labor pain intensity Timepoint With the onset of labor pain, the severity of pain is measured Method of measurement Visual Analogue Scale of Pain 2 Description Duration of labor Timepoint In 3 to 4 cm dilatation, the duration of labor is measured Method of measurement Partograph and checklist view and examination Secondary outcomes empty Intervention groups 1 Description
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Intervention group 1: Mindfulness-Based Stress Reduction Counseling: In primiparous women, 8 sessions will be held two days a week and sessions will last approximately 2.5 hours and severity of pain will be measured with Visual pain ruler and duration of labor will be compared using the partograph chart at the onset of labor in the active phase and compared with the control group

Category
N/A

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Description

Intervention group 2: auriculotherapy: At 4 cm dilatation and 40-37 weeks of gestational age, specific points on the ear are stimulated with vacarya sids (in traditional Chinese medicine, grainy labels of the plant Vakaria).

Category
N/A

3

Description

Intervention group 3: Use of flaxseed oil from Barich Company at 36-35 weeks of gestational age. Abdominal and lumbar massage with oil and training this work, three times a day

Category
N/A

4

Description

Control group: Treated in routine clinical practise

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Baft Khatamol Anbia Hospital

Full name of responsible person

Firoozeh Mirzaee

Street address

Payambare Azam boulevard, Imam street, Baft, Kerman

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7616913555

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2

Recruitment center

Name of recruitment center

Comprehensive Health Centers

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Firoozeh Mirzaee

Street address

Kerman University of Medical Sciences's Campus, Beginning of the Axis of the Haft Baghe Alavi

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7616913555

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Dr Firoozeh Mirzaee

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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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

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

Informed Consent Form

Undecided - It is not yet known if there will be 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