Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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; Sephalic 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)

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+98 34 4244 1785

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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 Sephalic 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
No information

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

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

2

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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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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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
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Person responsible for scientific inquiries

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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