# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Comparing the effect of foot trigger reflexology with aromatherapy on anxiety, pain and consequences of labor pregnancy in women

## Protocol summary

**Study aim**
Determining the effect of reflexology in reducing pain and anxiety of labor

**Design**
consecutive Clinical Trial study of multi-arm type randomized with one control and two intervention groups , on the 105 pregnant women without blinding. The random allocation was carried out by drawing lottery cards with tokens intervention1,2 and control group

**Settings and conduct**
The study was performed in the maternity ward of hospital in Firoozabad.The control group received routine care and in the two intervention groups, olive and lavender oil respectively were used for reflexology for 20 minutes for foot . Reflexology was performed at one time in 4-5 cm dilatation . Then, for the intervention and control groups, the pain and anxiety questionnaires were completed again in dilatation of 4-5 cm (immediately after the intervention) and 7-8 cm.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Primiparous mothers with full-term and single pregnancies with cephalic presentation who don't use analgesics to reduce pain. Exclusion criteria: History of miscarriage and high risk pregnancy

**Intervention groups**
the control group : routine maternity cares (control of contractions, fetal heart rate, monitoring labor progress and no palliative drug interventions), for the intervention group 1: routine cares along with using Reflexology technique of trigger points of Sole with non-aromatic oil (Olive oil) and the intervention group 2: routine cares along with Reflexology of trigger points of Sole with aromatic oil (Lavender oil).pressure at points of solar grid (at the border of the upper and middle third of the sole), pituitary point and uterus (between the inner ankle and the heel) was continued for a period of 20 minutes for each foot. Reflexology was taken place at one time in 4-5 cm dilatation.

**Main outcome variables**
Pain; anxiety; duration of the first and second stages of labor ; apgar score

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200810048357N1**
Registration date: **2020-10-05, 1399/07/14**
Registration timing: **retrospective**

Last update: **2020-10-05, 1399/07/14**
Update count: **0**

**Registration date**
2020-10-05, 1399/07/14

**Registrant information**

**Name**
Farzaneh Farahi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-07-18, 1398/04/27

**Expected recruitment end date**
2020-02-19, 1398/11/30

**Actual recruitment start date**
2019-07-18, 1398/04/27

**Actual recruitment end date**
2020-02-19, 1398/11/30

**Trial completion date**
2020-02-19, 1398/11/30

**Scientific title**
Comparing the effect of foot trigger reflexology with aromatherapy on anxiety, pain and consequences of labor pregnancy in women

**Public title**
Effect of reflexology on reducing labor pain

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
primigravida mothers having single term pregnancy with cephalic presentation The least dilatation of 4-5cm (the beginning of active phase of delivery No medical problems or pregnancy and fetal complications Without applying Analgesics and Anesthetics, Possessing psychical and cognitive ability to cooperate Having informed consent for participation

**Exclusion criteria:**
Miscarriage history High risk pregnancy

**Age**
No age limit

**Gender**
Female

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **105**
Actual sample size reached: **99**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Each mother was allocated randomly to one of the intervention or control groups. The random sampling was performed by drawing 105 cards labeled as intervention1,intervention 2 and control equally from a matte box .Thus the random sequence was not predictable.

**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 Kazeroon Islamic Azad University

**Street address**
Shahid Ghasem soleimani Blvd., Kazeroon azad university

**City**
Kazeroon

**Province**
Fars

**Postal code**
7319866451

**Approval date**
2019-07-16, 1398/04/25

**Ethics committee reference number**
IR.IAU.KAU.REC.1398.060

## Health conditions studied

### 1

**Description of health condition studied**
Labor pain

**ICD-10 code**
O75.8

**ICD-10 code description**
Other specified complications of labor and delivery

## Primary outcomes

### 1

**Description**
Labor pain

**Timepoint**
Pain were measured before intervention and then after intervention in 4- 5 and 7- 8 cm dilatation

**Method of measurement**
Visual analogue scale

### 2

**Description**
Anxiety

**Timepoint**
Anxiety was measured before intervention and then after intervention in 4-5 and 7-8 cm dilation

**Method of measurement**
Spielberger questionnaire

## Secondary outcomes

### 1

**Description**
Apgar score

**Timepoint**
Immediately after birth

**Method of measurement**
Using the Apgar score table

### 2

**Description**

Duration of the first stage of labor

**Timepoint**

Measure the time between dilatations 4-10 cm

**Method of measurement**

Time measurement

**3**

**Description**

Duration of the second stage of labor

**Timepoint**

From dilatation 10 cm to delivery

**Method of measurement**

Time measurement

## Intervention groups

**1**

**Description**

intervention group 1 : Routine cares along with reflexology technique of trigger points of sole with non-aromatic oil (olive oil)was continued for a period of 20 minutes for each foot. Reflexology with olive oil was taken place at one time in 4-5 cm dilatation

**Category**

Treatment - Other

**2**

**Description**

Intervention group2: Routine cares along with Reflexology technique of trigger points of Sole with aromatic oil (Lavender oil)was continued for a period of 20 minutes for each foot. Reflexology with Lavender oil was taken place at one time in 4-5 cm dilatation

**Category**

Treatment - Other

**3**

**Description**

Control group: routine maternity cares (control of contractions, fetal heart rate, monitoring labor progress, and no sedative drug interventions) performed Throughout the labor.

**Category**

N/A

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Ghaem Hospital

**Full name of responsible person**

Sajad Ahmadi

**Street address**

Pasdaran Ave ; Shahid Chegini blvd

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Firoozabad

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Ghareh Daghy Hossein

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gharehdaghy80@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Islamic Azad University

**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**

Islamic Azad University

**Full name of responsible person**

Farzaneh Farahi

**Position**

Faculty

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Yes - There is a plan to make this available
**Data Dictionary**
Not applicable
**Title and more details about the data/document**
Only part of the data that is related to the main outcome and is electronic will be available via e-mail after authentication and eligibility of the applicants.
**When the data will become available and for how long**
One year after the publication of the article and for one year the data will become available.
**To whom data/document is available**
Researchers and academics in universities
**Under which criteria data/document could be used**
Only systematic review and meta-analysis of data will be possible
**From where data/document is obtainable**
Call the number 0098 9367088289. Farahi farzaneh
**What processes are involved for a request to access data/document**
Having sufficient explanations and clarify their purpose for data analysis. additionaly presenting a formal request from a research institute or university.
**Comments**