

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Comparison the effect of foot solar plexus and H7 points reflexology on anxiety and pain amniocentesis

Protocol summary

Study aim

Comparison of the effect of reflexology of the solar plexus and H7 point network on anxiety and amniocentesis pain

Design

Clinical trial with a control group, single-blind, randomized,

Settings and conduct

The study lacks blindness, and pregnant women who go to the ultrasound office in Birjand City are randomly selected. mood Anxiety is measured at the beginning of the study immediately after and ten days after amniocentesis and Adjective anxiety is measured before and ten days after amniocentesis. pain is measured before and after amniocentesis.

Participants/Inclusion and exclusion criteria

Enter: Gestational age from 15 to 18 week The score obtained from the Dess 21 questionnaire (anxiety, depression and stress) must moderate and less Do not have multiple pregnancies Do not have amniocentesis experience No medical problem No obstetric complications Before the study, do not undergo foot reflexology or acupressure at the relevant point Expire: No Abnormal findings in the feet and hands The desire not to cooperate The research unit did not intervene Two consecutive times or for three consecutive days. Use of psychiatric medications during the intervention unusual sensitivity in the sole of the foot Try the needle for amniocentesis more than once.

Intervention groups

Intervention group 1: Foot reflexology in the solar plexus once 30 minutes before amniocentesis by the researcher for 20 minutes per foot 10 minutes. These units perform foot reflexology every day for 10 days as they were trained. Intervention group2: The acupressure on the H7 spot on the side of the ulnar bone and the Pisiform bone in the transverse fold line of the wrist is performed separately by the researcher for 5 minutes each hand for 30 minutes before performing amniocentesis. These

units perform foot reflexology every day for 10 days as they were trained.

Main outcome variables

Mood anxiety, adjective anxiety, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200401046914N1**

Registration date: **2020-04-17, 1399/01/29**

Registration timing: **prospective**

Last update: **2020-04-17, 1399/01/29**

Update count: **0**

Registration date

2020-04-17, 1399/01/29

Registrant information

Name

Mahla Salarfard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3243 5793

Email address

salarfard.ma@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of foot solar plexus and H7 points reflexology on anxiety and pain amniocentesis

Public title

Comparison the effect of foot reflexology and hand Acupressure on anxiety and pain amniocentesis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having at least Literacy for reading and writing
Gestational age from 15 to 18 week Maternal body mass index in the range 18.5-30 The score obtained from the Dess 21 questionnaire (anxiety, depression and stress) must moderate and less Not older than 38 years No smoking No active vaginal bleeding Do not have multiple pregnancies Do not have amniocentesis experience No medical problem No obstetric complications Before the study, do not undergo foot reflexology or acupressure at the relevant point. No history of mental disorders No history of psychiatric drugs No Abnormal findings in the foots and hands

Exclusion criteria:

The desire not to cooperate The research unit did not intervene Two consecutive times or for three consecutive days. Use of psychiatric medications during the intervention Lack of unusual sensitivity in the sole of the foot Try the needle for amniocentesis more than once.

Age

To 38 years old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Lottery for each group from one bag, day of the person or couple from another bag for sampling time

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**

committee of Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Moalem Street

City

Birjand

Province

South Khorasan

Postal code

9716813456

Approval date

2020-03-11, 1398/12/21

Ethics committee reference number<http://ethics.research.ac.ir/IR.BUMS.REC.1398.394>**Health conditions studied****1****Description of health condition studied**

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes**1****Description**

Anxiety Mood of Amniocentesis

Timepoint

At the beginning of the study, immediately after amniocentesis and ten days after amniocentesis

Method of measurement

Spielberger Mood Anxiety Questionnaire

2**Description**

Amniocentesis anxiety(Adjective)

Timepoint

At the beginning of the study, ten days after amniocentesis

Method of measurement

Spielberger Anxiety Questionnaire of Mode and adjective

3**Description**

Pain of Amniocentesis

Timepoint

Before and after amniocentesis

Method of measurement

Numerical scale of pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Foot reflexology in the solar plexus once 30 minutes before amniocentesis by the researcher for 20 minutes per foot 10 minutes. These units perform foot reflexology every day for 10 days as they were trained.

Category

Treatment - Other

2

Description

Intervention group: The acupressure on the H7 spot on the side of the ulnar bone and the Pisiform bone in the transverse fold line of the wrist is performed separately by the researcher for 5 minutes each hand for 30 minutes before performing amniocentesis. These units perform foot reflexology every day for 10 days as they were trained.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ultrasound clinic

Full name of responsible person

Mahla Salarfard

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Birjand School of Nursing and Midwifery, Moalem Street, Birjand City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Tooba Kazemi

Street address

Deputy of Research and Technology, Third Floor of Education and Research Building ,University of Medical Sciences, Birjand

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Mahla Salarfard

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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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