

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of foot reflexology on anxiety and pain of amniocentesis

Protocol summary

Study aim

Determination the effect of foot reflexology on anxiety and pain of amniocentesis in both intervention and control groups

Design

Randomized and 2 groups .no blind

Settings and conduct

The place to do reflexology is the ommolbanin of the hospital in Mashhad, 2 group,no blind

Participants/Inclusion and exclusion criteria

Research units with gestational age 18-15 weeks. No more than 38 years old. Cuts, burns, yeast infections, varicose veins, warts, compensating corns are not a kind of numbness in the foot;The research unit does not tend to cooperate during the study. The intervention did not complete two consecutive times or three interrupted sessions per week. Research unit has been used as a specific drug affecting mental medicine. The study is withdrawn.

Intervention groups

A total of twenty minutes per Dopa is done by the researcher. Mother in the lying situation back on the bed in a quiet room with enough light and a pillow under the foot to be comfortable, first a public massage for 2 minutes is done to prepare the legs, the purpose of the public massage, the surface touch massage, which has the same foreground movements to warm up the feet. By hand or carry out clear and conducting movements and under the foot with two hands, the foot turns outside and slips in the heel of massager. Then, a dedicated massage at the point of the solar plexus is a general reflexology for 7 minutes, at the end of a minute, a gentle move from top to bottom over the entire area of the back and sides of the foot with the help of the fingers of both hands and sixty.

Main outcome variables

Anxiety, Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190731044399N1**

Registration date: **2019-08-21, 1398/05/30**

Registration timing: **prospective**

Last update: **2019-08-21, 1398/05/30**

Update count: **0**

Registration date

2019-08-21, 1398/05/30

Registrant information

Name

Marzie Samieean

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3290 0570

Email address

marziesamieean@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-01, 1398/06/10

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology on anxiety and pain of

amniocentesis

Public title
foot reflexology on anxiety and pain of amniocentesis

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Research units with gestational age of 18-15 weeks The mother suffers from horrible incidents over the past 6 months No more than 38 years old Do not have a midwife problem in the current pregnancy Not a history of mental disorder No genetic problem at family class1 Cuts, burns, yeast infections, varicose veins, warts, compensating corns are not a kind of numbness in the feet Do not have a history of recurrent abortion (more than 3 consecutive miscarriages)
Exclusion criteria:

Age
To **38 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
The subjects with inclusion criteria were entered into the study in an easy way. , The selection of weekdays for people is done accidentally, as if the lottery was taken to remove any number of bags, if the number was paired in the intervention group and if the person was in the control group.

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 Mashhad University of Medical Sciences

Street address

Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9777165535

Approval date

2019-08-05, 1398/05/14

Ethics committee reference number

IR.MUMS.NURSE.REC.1398.042

Health conditions studied

1

Description of health condition studied

anxiety and pain

ICD-10 code

ICD-10 code description

CHAPTER V(Mental and behavioural disorders)F40-F48

Neurotic, stress-related and somatoform disordersF41

Other anxiety disordersF41.1 Generalized anxiety disorder

Primary outcomes

1

Description

Anxiety

Timepoint

Before and after intervention

Method of measurement

STAI questionnaire

Secondary outcomes

1

Description

Pain

Timepoint

After intervention

Method of measurement

Visual analogue scale

Intervention groups

1

Description

Intervention group:The foot reflexology on the solar plexus is one time thirty minutes before the amniocentesis done by the researcher for 20 minutes every 10-minute foot. Foot reflexology is done by pressure and massage of solar پلکسوس area (sunnet). To reduce the friction of a non-volatile oil drop, the baby's oil is used before starting the work. In this research, reflexology starts from the left foot, conducting the massage in every foot ten minutes, totaling twenty minutes per dopa by the researcher. Mother in the lying situation back on the bed in a quiet room with enough light and a pillow under the foot to be comfortable, first a

public massage for 2 minutes is done to prepare the legs, the purpose of the public massage, the surface touch massage, which has the same foreground movements to warm up the feet. By hand or carry out clear and conducting movements and under the foot with two hands, the foot turns outside and slips in the heel of *وهمجين* massager. Then, the private massage in the solar grid point is a general reflexology for 7 minutes, at the end of a minute, a gentle move from top to bottom over the entire area of the back and sides of the foot with the help of both hands and sixty

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ommolbanin Hospital

Full name of responsible person

Marzie Samieean

Street address

Faculty of Nursing Midwifery

City

Mashhad

Province

Razavi Khorasan

Postal code

9777165535

Phone

+98 56 3290 0570

Email

marziesamieean@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Samieean Marzie

Street address

Faculty of Nursing Midwifery

City

Mashhad

Province

Razavi Khorasan

Postal code

9777165535

Phone

+98 56 3290 0570

Email

AbedianZ@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Abedian Zahra

Position

Teacher

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9378191331

Phone

+98 51 3859 1511

Email

AbedianZ@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Abedian Zahra

Position

Master

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9378191331

Phone

+98 51 3852 8511

Email

marziesamieean@yahoo.com

+98 51 3852 8511

Email

marziesamieean@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Samieean Marzie

Position

Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Mashhad

City

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Province

Razavi Khorasan

Postal code

9378191331

Phone**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