

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Investigation of the effect of acupressure on pain intensity and anxiety in hospitalized women in Niknafs maternity hospital in Rafsanjan, 2020

Protocol summary

Study aim

Determining the effect of acupressure on the intensity of pain and anxiety caused by abortion in women hospitalized in Nik Nafs maternity hospital in Rafsanjan

Design

A randomized, double-blind, randomized controlled clinical trial on 120 patients will be performed to randomize the first-person lottery in each score in the pretest and continue with the prepared pain chart.

Settings and conduct

This study is a randomized clinical trial with the control group that is performed in Nik Nafs maternity hospital in Rafsanjan on cases of induced and spontaneous abortion, which are hospitalized and the questioner and the patient are unaware of the assignment of groups.

Participants/Inclusion and exclusion criteria

Single pregnant women who are having an abortion and have a pain score higher than 3 and do not have a known systemic or mental illness and are willing to participate in the study, enter the study. Cases of severe bleeding at admission, Taking any sedative before entering the study, septic abortion cases Will not enter the study

Intervention groups

For the intervention group, acupressure is applied bilaterally at point LI4 in periods of 10 seconds of pressure and 2 seconds of rest for 20 minutes. For the touch group, non-pressure touch at the same points in the intervention group and at the same times, and for the control group, they will not receive any intervention except routine ward care.

Main outcome variables

Pain and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210310050657N1**

Registration date: **2021-12-01, 1400/09/10**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-01, 1400/09/10**

Update count: **0**

Registration date

2021-12-01, 1400/09/10

Registrant information

Name

Zohreh Sahebi Sham abadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3420 0375

Email address

sahebizm@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-21, 1400/08/30

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Investigation of the effect of acupressure on pain

intensity and anxiety in hospitalized women in Niknafs maternity hospital in Rafsanjan, 2020

Public title

The Effect of Acupressure on Abortion

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 18 to 45 years Hospitalization with a diagnosis of spontaneous or induced abortion Having a pain score higher than 3 based on the VAS scale Single pregnancy Gestational age less than 20 weeks based on LMP or ultrasound No lesions at the site of acupressure Having enough cognitive power to answer research questions No drug and alcohol abuse No history of known mental illness

Exclusion criteria:

Cases of severe bleeding at admission Taking any sedative before entering the study septic abortion cases

Age

From 18 years old to 45 years old

Gender

Female

Phase

N/A

Groups that have been masked

• Participant

• Outcome assessor

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be done by randomly minimization method, based on the pre-test pain score classes (i.e., severe and moderate). Randomization units will be entered into the study individually. The first sample will be allocated to each class in one of the study groups by random lottery through the sealed envelope. The arrival of the next sample with the same pre-test pain class between the two remaining groups will also be done by lottery. The third sample with the same attribute will be assigned to the last group in the same category. This process will continue until the desired sample size is reached. It is noteworthy that the samples will not be aware of how they will be assigned into the groups

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, only acupressure specialist is aware of the allocation of samples. Samples and questioners will be unaware of samples' allocation in the groups. The questioner will fill in the questionnaire and is unaware of the allocation of samples in groups. Then, the acupressure expert will randomly place the samples in intervention, touch, and control groups and perform specific actions for each group. It is of note that the patients are also unaware of the group they belong to.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

NO38, Northern Meraj 40. Bahonar Blvd

City

Rāfsanjan

Province

Kerman

Postal code

7719678375

Approval date

2020-09-14, 1399/06/24

Ethics committee reference number

IR.RUMS.REC.1399.147

Health conditions studied

1

Description of health condition studied

Abortion

ICD-10 code

O02.1

ICD-10 code description

Missed abortion

Primary outcomes

1

Description

Pain during abortion

Timepoint

Measurement of previous pain, immediately after and 30 minutes after the intervention.

Method of measurement

The data collection tool will consist of three parts. The first part contains the demographic information questionnaire, the second part contains the 10-point visual instrument for measuring pain (VAS). The third part includes the Spielberger Anxiety Standard Questionnaire.

Secondary outcomes

1

Description

Anxiety

Timepoint

Before the commence of intervention, immediately after the intervention and 30 minutes after the finishing of intervention.

Method of measurement

Spielberger Anxiety Standard Questionnaire

Intervention groups

1

Description

Intervention group: Acupressure at LI4 point (in middle of the angle between the first and second bones of the palm between the thumb and index finger on the back of the hand) bilaterally in periods of 10 seconds of pressure and 2 seconds of rest, for 20 minutes in a row It is applied to the extent that the specimens have a feeling of warmth and mild pain and pressure.

Category

Other

2

Description

Touch group: For the touch group, non-pressure touch will be performed at LI4 point similar to the intervention group and with the same times, in 20 minutes

Category

Other

3

Description

Control group: For the control group, they will not receive any intervention other than routine ward care (taking a vein, requesting CBC, connecting Ringer's serum at the time of starting bleeding). The questionnaire will be filled in at 0, 20 and 50 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Nik Nafs Maternity Hospital

Full name of responsible person

Zohreh Sahebi Sham Abadi

Street address

No.38, North Meraj Ave., Bahonar Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice Chancellor of Research and Technology of Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Zohreh Sahebi Sham Abadi

Position

Science Committee

Latest degree

Master

Other areas of specialty/work

Midwifery

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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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No information available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available