Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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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
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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
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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