

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effect of auricular acupressure on anxiety and pain during dressing change in burn victims in critical care unit

Protocol summary

Study aim

Determining the effect of acupressure on the pain and anxiety caused by changing the dressing in burn victims.

Design

Clinical trials with control group, randomized, parallel groups, double blinded

Settings and conduct

This interventional study is a three-group double-blind clinical trial, designed to determine the effect of ear acupressure on the pain and anxiety caused by dressing change in burned patients. The statistical population of this study includes the patients hospitalized in the burn intensive care unit of Zare Hospital in Sari. The statistics specialist and assessor are blind to the intervention

Participants/Inclusion and exclusion criteria

Inclusion Criteria: aged over 18, alert, unintentional burns of grade 2 and 3 less than 35%, being in the acute phase of burn, The absence of a history of mental disorders, including depression and anxiety, Having a natural auricle without lesion and pain, Lack of use of acupressure in the past, no burns on face, neck, and ears. Exclusion Criteria: Drug Addiction, Pregnancy

Intervention groups

The intervention includes ear acupressure and control group only receive the routine care about pain relief.

Main outcome variables

Pain and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180228038898N1**

Registration date: **2018-08-05, 1397/05/14**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-05, 1397/05/14**

Update count: **0**

Registration date

2018-08-05, 1397/05/14

Registrant information

Name

Mohammadreza Zakeri Sanate

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3332 6817

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of auricular acupressure on anxiety and pain during dressing change in burn victims in critical care unit

Public title

The effect of auricular acupressure on anxiety and pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

aged over 18, alert, unintentional burns of grade 2 and 3

less than 35%, being in the acute phase of burn, The absence of a history of mental disorders, including depression and anxiety, Having a natural auricle without lesion and pain, Lack of use of acupressure in the past, no burns on face, neck, and ears.

Exclusion criteria:

Drug Addiction, Pregnancy

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

The eligible patients are selected using convenience sampling method and then, using random numbers table, samples will be divided into three groups A, B and C.

Blinding (investigator's opinion)

Double blinded

Blinding description

The statistician is also blind to the intervention. Variables are measured by the assessor (a trained nurse) who is blind to blind intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences

Street address

Start of valiye asr highway, Imam Square, Sari, Mazandaran

City

Sari

Province

Mazandaran

Postal code

4736131167

Approval date

2018-06-20, 1397/03/30

Ethics committee reference number

IR.MAZUMS.REC.1397.001

Health conditions studied

1

Description of health condition studied

Burns and corrosions

ICD-10 code

T20-T32

ICD-10 code description

Burns and corrosions

Primary outcomes

1

Description

pain

Timepoint

30 minutes before the intervention, immediately after the dressing, 15 minutes, 30 minutes and 60 minutes after

Method of measurement

visual analouge scale

2

Description

anxiety

Timepoint

30 minutes before the intervention, immediately after the dressing, 15 minutes, 30 minutes and 60 minutes after

Method of measurement

Burn specific Pain Anxiety Scale

Secondary outcomes

1

Description

blood pressure

Timepoint

Before the intervention and 60 minutes after the intervention

Method of measurement

Barometer device

2

Description

Pulse

Timepoint

Before the intervention and 60 minutes after the intervention

Method of measurement

Touch

Intervention groups

1

Description

Intervention group: the patients in the intervention group receive acupressure at the Shenmen point in the upper wall of the ear cavity. The method of applying pressure to the units under study in the intervention group is that the researcher pushes the finger using the index finger on the stench of the ear for two minutes so that the person feels heavy, warm, or numb.

Category

Treatment - Other

2

Description

Intervention group: The sham group receives acupressure treatment in a false point; which is not effective according to acupressure philosophy. This point is at the beginning of the ear cavity.

Category

Treatment - Other

3

Description

control group: only receive the routine care about pain relief.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Zare Hospital

Full name of responsible person

Mohammad Reza Zakeri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr.Ahmadali Enayati

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Moalem Street ,Moalem Square

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4814766665

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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

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Mohamad Reza Zakeri

Position

MSC in Critical Care Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

PHD in nursing/ faculty member

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

Mazandaran University of Medical Sciences

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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