# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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 legion 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)
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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 legion 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

**Street address**
Imam Reza Blvd

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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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**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

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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