Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 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)
Phone
+98 11 3332 6817
Email address
m.zakeri@mazums.ac.ir

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

City
Sari

Province
Mazandaran

Postal code
481476665

Phone
+98 11 3328 3886

Email
zakerimohamadreza@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Dr.Ahmadali Enayati

Street address
Moalem Street ,Moalem Square

City
Sari

Province
Mazandaran

Postal code
4814766665

Phone
+98 11 3332 6817

Email
tf@mazums.ac.ir

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

Street address
Nasibeh School of Nursing and Midwifery, , Sari

City
Sari

Province
Mazandaran

Postal code
48197-53171

Phone
+98 11 3336 7342

Email
zakerimohamadreza@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Dr. Seyed Afshin Shorofi
Position
PHD in nursing/ faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Nasibeh School of Nursing and Midwifery, Vesal Shirazi Street, Sari, Mazandaran
City
Sari
Province
Mazandaran
Postal code
48197-53171
Phone
+98 11 3336 7342
Email
afshinshorofi@gmail.com

Person responsible for updating data

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
Street address
Nasibeh School of Nursing and Midwifery, , Sari
City
Sari
Province
Mazandaran
Postal code
48197-53171
Phone
+98 11 3332 6817
Email
zakerimohamadreza@yahoo.com

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