

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### The effects of family presence on pain and pain anxiety dressing of patient in burn intensive care unit in zare hospital

#### Protocol summary

##### Summary

The aim of this Randomized Clinical Trial is to determine the effect of family attendance on pain and anxiety arising from the pain of dressing change of patients from intensive care ward in ZARE HOSPITAL of SARI. Inclusion Criteria: All patients over 18 years old, alert, burn more than 10% Grade 2 and 3 with moderate and severe burns. Exclusion Criteria: Drug Addiction, A History of Severe Mental Illness, Mental Retardation and Cognitive, Respiratory Distress, Intubated, Infection of the Wound, Transfer, Discharge and Death. Sample: 110 Patients are in two groups each (n = 55) based on random assignment experimental and control groups. On third day of admission, participants (preferably relative) in the event of not having severe anxiety entered in the study. Then, training includes the patient's condition, the provisions of section, treatment of patients with wound dehiscence, infection control precautions including hand washing, entry requirements and duration of the clinical evaluation of the patient's manipulation of joints, participation in nutrition as primary care offered by the researcher. In the intervention group, from fourth day of hospitalization, a family member for 5 consecutive days in one-hour meetings and before dressing will be present at bedside of the patient. Control group (without mobile) will be treated. Anxiety and pain caused by burns after pain and 15 minutes before dressing, and intensity immediately before and after dressing for 6 consecutive days (3rd to 8th days) in the two groups will be discussed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201602297494N17**

Registration date: **2016-05-18, 1395/02/29**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-05-18, 1395/02/29

##### Registrant information

###### Name

Masoumeh Bagheri Nesami

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3336 7551

###### Email address

mbagheri@mazums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Mazandaran University of Medical Sciences

##### Expected recruitment start date

2016-03-05, 1394/12/15

##### Expected recruitment end date

2016-08-21, 1395/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of family presence on pain and pain anxiety dressing of patient in burn intensive care unit in zare hospital

##### Public title

The effects of family presence on pain and pain anxiety dressing of patient in burn intensive care unit

##### Purpose

Supportive

**Inclusion/Exclusion criteria**  
 Inclusion Criteria: All patients over 18 years old, alert, burn more than 10% Grade 2 and 3 with moderate and severe burns. Exclusion Criteria: Drug Addiction, A History of Severe Mental Illness, Mental Retardation and Cognitive, Respiratory Distress, Intubated, Infection of the Wound, Transfer, Discharge and Death.

**Age**  
 From **18 years** old

**Gender**  
 Both

**Phase**  
 N/A

**Groups that have been masked**  
*No information*

**Sample size**  
 Target sample size: **110**

**Randomization (investigator's opinion)**  
 Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
 Not blinded

**Blinding description**

**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

##### Postal code

4736131167

#### Approval date

2016-02-21, 1394/12/02

#### Ethics committee reference number

IR.MAZUMS.REC.94-2126

## 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

Burn pain anxiety

#### Timepoint

15 minutes before dressing change from the third to the eighth hospitalization day

#### Method of measurement

Burn specific Pain Anxiety Scale

### 2

#### Description

Pain

#### Timepoint

Immediately before and after dressing change from the third to the eighth hospitalization day

#### Method of measurement

Visual Analog scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The one-hour-presence of the patient's desired attendant at bedside for five consecutive days before dressing by observing train cases from 4th to 8th hospitalization day.

#### Category

Other

### 2

#### Description

The absence of attendant in a control group with will perform.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Zare Hospital

##### Full name of responsible person

Masoomah Koohi

##### Street address

Zare Hospital, sari

##### City

Sari

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice Chancellor for Research Mazandaran University of Medical Sciences.

**Full name of responsible person**

Dr.Ahmadali Enayati

**Street address**

Vice Chancellor for research Mazandaran University of Medical Sciences, Moalem Street ,Moalem Square,Sari, Iran.

**City**

Sari

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for Research Mazandaran University of Medical Sciences.

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Masoomah Koohi

**Position**

MSC in Critical Care Nursing

**Other areas of specialty/work****Street address**

Nasibeh School of Nursing and Midwifery, , Sari

**City**

Sari

**Postal code**

48197-53171

**Phone**

+98 11 3336 7342

**Fax****Email**

m.koohi61@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr Masoumeh Bagheri Nesami

**Position**

PHD in nursing/ faculty member

**Other areas of specialty/work****Street address**

Nasibeh School of Nursing and Midwifery, Vesal Shirazi Street, Sari, Mazandaran

**City**

Sari

**Postal code****Phone**

+98 11 3336 7342

**Fax**

+98 15 1226 8915

**Email**

anna30432003@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*