

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Family Attending Burn ICU Inpatient Influencing Family Anxiety.

Protocol summary

Summary

The present random clinical trial pursues the goal to outline the effect of family attending Burn ICU inpatients on family anxiety in Sari based Zaare Hospital. The inclusion criteria: all attendants are over 18 yrs; conscious; The exclusion criteria: addiction; the patient and the attendant having a record of severe mental disorder, mentally and cognitively impaired; respiratory distress, intubation, wound infection, transfer, regulations, not observing the infection control precautions. Sample: 60 patients will be randomly allocated in to intervention and control groups (each with 30 subjects). Then the training will be presented by the researcher on how to handle patient's open wound, standard infection control precautions, especially for hand washing, and participating in nutrition as the primary care. In the intervention group, the family attends the inpatient for 5 consecutive 1-h session days and before wound dressing from the 4th to the 8 hospitalization day. In the control group, the ward routine is followed (no family attendance). The patient's attendants' anxiety in the two groups will be measured via Spielberg anxiety inventory (the 3rd and 8th hospitalization day).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201605017494N18**
Registration date: **2016-09-08, 1395/06/18**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-08, 1395/06/18

Registrant information

Name

Masoumeh Bagheri Nesami

Name of organization / entity

Mazandaran University of Medical Sciences

Country

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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

2016-06-04, 1395/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Family Attending Burn ICU Inpatient Influencing Family Anxiety.

Public title

Family Attending Burn ICU Inpatient Influencing Family Anxiety.

Purpose

Supportive

Inclusion/Exclusion criteria

The inclusion criteria: all attendants are over 18 yrs; conscious; The exclusion criteria: addiction; the patient and the attendant having a record of severe mental disorder ; mentally and cognitively impaired ; respiratory distress; intubation; wound infection; transfer; regulations; not observing the infection control precautions.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Ethics Committee of Mazandaran University of
Medical Science

Street address

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

City

Sari

Postal code

4736131167

Approval date

2016-02-23, 1394/12/04

Ethics committee reference number

IR.MAZUMS.REC.95.S 103

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F90-F98

ICD-10 code description

Behavioural and emotional disorders with onset usually
occurring in childhood and adolescence

Primary outcomes

1

Description

Anxiety

Timepoint

At the 3th and 8th day of admission

Method of measurement

Spielberger anxiety inventory

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

Routine control group (without patient's family) to be
treated.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Zare Hospital

Full name of responsible person

Masoomeh 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 Koochi

Position

MSC in Critical Care Nursing

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

Nasibeh School of Nursing and Midwifery, , Sari

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PHD in nursing/ faculty member

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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