Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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MSC in Critical Care Nursing
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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