Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effectiveness of spiritual care on family satisfaction in intensive care units

Protocol summary

Study aim
Determining the effect of spiritual care on satisfaction of the family of patients admitted to the Poursina Pediatric Hospital in 2018

Design
A clinical trial with a sample size of 45 people in the intervention(spiritual care)and control group(Receive routine care), random allocation in four blocks

Settings and conduct
The standard family satisfaction questionnaire for hospitalized patients in the Pursina Hospital before the intervention is completed by both intervention and control groups. After providing spiritual care for three days, the questionnaire was re-entered into both intervention and control groups

Participants/Inclusion and exclusion criteria
Entry requirements:A close relative (father, mother, spouse or child) is a patient who has been admitted to the intensive care unit for at least three days And the score for multiple organ dysfunction syndrome between 13 and 24, the continuous presence of the family member in the hospital during the study period; No entry criteria:A family member is not a close relative (father, mother, spouse or child), A member of the patient's family who does not have a continuous presence during the course of the study in the hospital, The patient is admitted to the intensive care unit for less than three days, Multiple organ dysfunction syndrome score less than 13

Intervention groups
Intervention group:The spiritual care program includes: supporting support, support for religious ceremonies for the patient's family, use of supportive systems Control group: The hospital's usual plans will be implemented.

Main outcome variables
Family satisfaction of patients hospitalized in intensive care units

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140310016917N5**
Registration date: **2018-09-11, 1397/06/20**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-11, 1397/06/20**
Update count: **0**

Registration date
2018-09-11, 1397/06/20

Registrant information

Name
Ali Ashraf

Name of organization / entity
Guilan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 13 1321 0434

Email address
aliashraf@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-23, 1397/06/01

Expected recruitment end date
2018-10-23, 1397/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of spiritual care on family satisfaction in intensive care units

Public title
Effectiveness of spiritual care on family satisfaction in intensive care units

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
One of the close relatives of patient admitted to the intensive care unit who was admitted three days before the start of the study The Multi-Organ Dysfunction Syndrome score of the patient admitted between 13 and 24 to match the severity of the disease Persian Language of family member Have reading and writing skills Not having severe and severe mental and psychological problems Lack of blindness and deafness

Exclusion criteria:
The family of patients is very sick with a MODS score of less than 13 Failure to understand and speak Persian Not having the least reading and writing skills Having severe mental and emotional problems Blindness or deafness Stay less than 3 days in the intensive care unit

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation of Quadruple blocks in two groups of intervention and control, after determining the random sequences, each sequence on a card inside a sealed envelope will be hidden.

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 Guilan university of medical scienecs

Street address
Parashtar street, Poursina Hospital

City
Rasht

Province
Guilan

Postal code
41937-13194

Approval date
2018-08-01, 1397/05/10

Ethics committee reference number
IR.GUMS.REC.1397.168

Health conditions studied

1

Description of health condition studied
Satisfaction of the family of patients admitted to the intensive care unit

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Satisfaction

Timepoint
Before the intervention and the day after the end of the intervention

Method of measurement
Using the family satisfaction questionnaire for patients in the intensive care unit, FS-ICU

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receive spiritual care

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Poursina Haspital

Full name of responsible person
ali ashraf

Street address
Parastar street, Poursina hospital

City
Rasht
Province
Guilan
Postal code
41937-13194
Phone
+98 13 3332 2444
Email
aliashraf@gums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Deputy of Research and Technology of Guilan University of Medical Sciences
Street address
Parastar
City
Rasht
Province
Guilan
Postal code
41937-13194
Phone
+98 13 3332 2444
Email
research@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
ali ashraf
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Parastar
City
Rasht
Province
Guilan
Postal code
41937-13194
Phone
+98 13 3332 2444
Email
aliashraf@gums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
ali ashraf
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Parastar
City
Rasht
Province
Guilan
Postal code
41937-13194
Phone
+98 13 3332 2250
Email
aliashraf@gums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
ali ashraf
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Parastar
City
Rasht
Province
Guilan

Postal code
41937-13194
Phone
+98 13 3332 2250
Email
aliashraf@gums.ac.ir

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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable