Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigation the effect of conducted meeting of family on the level of consciousness patients in ICU

Protocol summary

Summary

The aim of this study is to identify the effect of conducted family meeting on the level of consciousness in comatose patients with traumatic brain. The sample consisted of 64 patients with focal brain lesions following head injury are admitted in the intensive care units of Al-Zahra and Kashani hospital. Patients in the intervention and control groups (each n = 32) will be placed with randomization. Selection criteria included patients aged 65-15 with a Glasgow Coma Scale score of 8-5 within 24 hours after admission and not to have a history of hospitalization in the ICU. Patient in intervention group receive auditory and tactile stimulation for 45-60 minutes once the patient is meted with a family member for 14 days. In control group, in routine way, meetings with the family will be every other day for 30 minutes. Conciousness level will be measured a half hour before and after each meeting (twice daily) with Glasgow Coma Scale score and 4 score. The mean GCS score and 4score before and after the meetings is statistically determined and analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014091719208N1**
Registration date: **2015-01-25, 1393/11/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-01-25, 1393/11/05

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Shaheed Sadoughi University Of Medical Sciences and Health Services, Yazd, Iran.

Expected recruitment start date

2014-09-27, 1393/07/05

Expected recruitment end date

2014-12-26, 1393/10/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of conducted meeting of family on the level of consciousness patients in ICU

Public title

Guided visit family impact awareness

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Coma associated with scalp focal damage; patients aged 65-18 years; GCS 5-8; less than 24 hours of admission in ICU. Exclusion Criteria: History of hospitalization in ICU.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Yazd University of Medical Sciences and Health Services martyr
Street address
Yazd-of-the-art martyr doctor at the Central University of Medical Sciences and Health Services, Tel 7240171 Fax: 7254750 8916978477 martyr Sadooghi Yzdkdpsty
City
Yazd
Postal code
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Approval date
2014-06-25, 1393/04/04
Ethics committee reference number
17/1/65419پ

Health conditions studied

1

Description of health condition studied
brain injury patients admitted to the ICU
ICD-10 code
s06.3
ICD-10 code description
S06.3 Focal brain injury Focal: cerebral: contusion laceration traumatic intracerebral haemorrhage S06.4 Epidural haemorrhage Extradural haemorrhage (traumatic) S06.5 Traumatic subdural haemorrh

Primary outcomes

1

Description
Patient's level of consciousness
Timepoint
Daily, half an hour before and after the intervention.
Method of measurement
Glasgow coma scale and 4scoure

Secondary outcomes

empty

Intervention groups

1

Description
Daily conducted family meeting, 45 minutes to an hour (at 17-16 o'clock) for 14 days. In a training session, one of the family member with more emotional relationship with the patient will be trained about the general condition, ICU equipments, infection control necessarily met during the meeting, sensory stimulation can be used and expression of effective sentences. In the first meeting, family member accompanied by researcher. After mentally and emotionally stability, the researcher explains and practically demonstrates expected arrangement of care.
Category
Rehabilitation

2

Description
The control group received the usual meeting in accordance with the rules of ICU. Three times a week, 30 minutes, 15-15.30 o'clock.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospital Al Zahra
Full name of responsible person
Street address
City
Esfahan

2

Recruitment center
Name of recruitment center
Ayatollah Kashani Hospital
Full name of responsible person
Street address

City
Esfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research deputy of university Medical Sciences, Yazd
Full name of responsible person
Dr. Amir Hooshang Mehrparvar
Street address
Shaheed Sadoughi University of Medical Sciences and Health Services, Shaheed Dr. Ba Honar sq., Yazd, Iran,
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research deputy of university Medical Sciences, Yazd
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
Yazd Shahid Sadoughi University of Medical
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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