Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of the family participation based on affective stimulations on improving the level of consciousness patients with brain trauma.

Protocol summary

Summary

Objectives: The objective of the study is to determine the effectiveness of the family participation based on affective simulations on improving the patients with brain trauma hospitalized in ICUs. Design: This study is conducted as a combined embedded study in which the qualitative part of the study is of the clinical trial type and at least 60 patients with brain trauma were put in three groups (intervention, control and placebo groups) by permutated sampling method as randomly. This study is as a triple blind study in which the patient, researcher and information analyzers are not informed of the intervention received by the patient. Setting and Conduct: In intervention group, the family participation has been made through regular visits and establishing defined communications with the patient in two morning and afternoon times for 7 days by a close member of the family and in placebo group the same intervention was done by a strange person and also, in control group the visit will be made as is routine in ICUs (from behind the window). Participants: Inclusion criteria include the brain trauma patients having level of consciousness based on Glasgow Coma Scale between 5 -8 and the family of these patients must be the first degree members of the patients (father, mother, sister, brother, child, wife/husband) and exclusion criteria include the death of patient, transferring of patient to the other centers during the study, and operating a surgery during the study. Main outcome measures: Before and immediately after the intervention, the level of consciousness the patients would be measured using two tools: Glasgow Coma and recovery Coma scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201503048069N3**

Registration date: **2016-02-01, 1394/11/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-01, 1394/11/12

Registrant information

Name

Fatemeh Salmani

Name of organization / entity

Esfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tarbiat Modares University

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the family participation based on affective stimulations on improving the level of consciousness patients with brain trauma.

Public title

Evaluating of the family participation based on affective simulations on improving the level of consciousness patients with brain trauma hospitalized in ICUs: A combined embedded study.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Family inclusion criteria: He/She can be considered as the first degree relative of the patient (father, mother, sister, brother, child, wife/husband) , having the ability of verbal communication with the others, the age of relative would be in the range of 18 and lower than 65 years old. Patients' inclusion criteria: Hospitalizing with Head injury (brain trauma) diagnosis, the level of consciousness based on Glasgow Coma Scale between 5 -8, the age of patient between 18-65 years old. Exclusion criteria: The death of patient during the study, transferring of patient to the other centers during the study, operating a surgery during the study, withdrawing the patient's family to continue to participate in the study, discharge of patient from the unit before 7 days of hospitalization time, having background diseases such as Alzheimer, Parkinson, brain stroke and so on.

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Medical of Science of Tarbiat Modares University

Street address

Tarbiat Modares University, Nasr Bridge, Tehran

City

Tehran

Postal code

Approval date

2015-04-28, 1394/02/08

Ethics committee reference number

IR.TMU.REC.1394.22

Health conditions studied

1

Description of health condition studied

Head trauma

ICD-10 code

S00-S09

ICD-10 code description

Injuries to the head

Primary outcomes

1

Description

Level of consciousness

Timepoint

Twice a day,before and immediately after the intervention

Method of measurement

By Glasgow Coma Scale and Coma Recovery Scale

Secondary outcomes

1

Description

Length of stay in the intensive care unit

Timepoint

Once, when discharged from ICU

Method of measurement

By Level of Consciousness Questionnaire

Intervention groups

1

Description

In intervention group, family participation through Regular visits and establishing defined communications with the patient as sensory and affective simulations are done by a close member of the family twice a day (morning and evening) for 7 days. : Before and immediately after the intervention, the level of consciousness the patients would be measured using two tools: Glasgow Coma and recovery Coma scale.

Category

Treatment - Other

2

Description

In placebo group, visit and sensory simulations are made by an unfamiliar trained person who has no affinity,

affective and family relations with the patients twice a day (morning and evening). Before and immediately after the intervention, the level of consciousness the patients would be measured using two tools: Glasgow Coma and recovery Coma scale.

Category

Treatment - Other

3

Description

In control group, care and visit would be made as is routine in ICUs (the family visit from behind the window and from the distant). Before and immediately after the intervention, the level of consciousness the patients would be measured using two tools: Glasgow Coma and recovery Coma scale.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Azahra Hospital

Full name of responsible person

Dr Majeed Rezvani

Street address

Sofeh street, Alzahra hospital,Esfahan

City

Esfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, University of Tarbiat Modares

Full name of responsible person

Dr Mansoreh Movahedin

Street address

University of Tarbiat Modares, Nasr Bridge, Tehran

City

Tehran

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, University of Tarbiat Modares

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

Tarbiat Modares University

Full name of responsible person

Mansoreh Movahedin

Position

Vice chancellor for research

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Person responsible for updating data

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Fatemeh Salmani

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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