

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of Regular meeting of Families on Physiological Parameters and Recovery Process in non-ventilated CVA Patients in ICU

Protocol summary

Summary

(1)Objectives:This designed study aimed to the effect of regular meeting of families on Physiological Parameters and Recovery Process in non-ventilated CVA Patients in ICU. (2)Design:Intensive care unit patients are faced with many stressors which includes artificial light during 24 hours, Continuous noise monitoring machine and respiratory support, lack of meaningful stimulus as touched by members of family and Physical pain or discomfort caused by disease. The volume of the sample for each group is stated 28 but it is considered that there might be a reduction in the sample of 34 in each group. (3)Setting and conduct:The presence of family members(to have Strong emotional relationship with a person hospitalized)In intensive care units two times per day in the first six Admission Besides patient and doing Trained health care activities (4)Inclusion criteria included: Family consent for participating in research:non-ventilated patient:older than 18 years:not part of the clinical staff. Exclusion criteria:Require mechanical ventilation during the research:death of patient:transferred to other hospitals:withdrew from participation in the study for any reason. (5)Intervention included:Care activities such as Tactile contact with the patient during care, cleaning the eyes of patients with wet sterile gauze, Use Softener hands and feet in patients. (6)main outcome measures (variables) Included:Physiological Parameters and Scale Recovery Process

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122715954N1**

Registration date: **2014-03-09, 1392/12/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-09, 1392/12/18

Registrant information

Name

Mohammad Reza Jani

Name of organization / entity

Medical University Gonabad

Country

Iran (Islamic Republic of)

Phone

+98 53 3722 3513

Email address

jani.m@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Medical University Gonabad, Vice chancellor for Research

Expected recruitment start date

2013-08-22, 1392/05/31

Expected recruitment end date

2014-05-05, 1393/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Regular meeting of Families on Physiological Parameters and Recovery Process in non-ventilated CVA Patients in ICU

Public title

Effect meets on improving patient meets

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Family Satisfaction for participating in research: non-ventilated patient: the presence of family members at the meeting (spouse, mother, father, son, brother and sister): no underlying disease was diagnosed as cancer, tuberculosis, hepatitis (Patient): first-degree relatives (spouse, mother, father, son, sister, brother): older than 18 years: not part of the clinical staff: not suffering members of family from The mood disorder - emotional diagnosed that prevent from effective communication: not suffering from a cold visitors: patient is having nasal-gastric catheter.
Exclusion criteria: Require mechanical ventilation during the research: discharged before the sixth day of the ICU: death of patient: Transferred to other hospitals: withdrew from participation in the study for any reason

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **68**

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 the Medical University Gonabab

Street address

Medical University Gonabad, Vice chancellor for Education and Research, road edges, Asian, Khorasan Razavi, Gonabad

City

Gonabad

Postal code

9691793718

Approval date

2013-12-25, 1392/10/04

Ethics committee reference number

gmu.rec.1392.21

Health conditions studied

1

Description of health condition studied

Cerebrovascular accidents

ICD-10 code

I64

ICD-10 code description

Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description

Improving process

Timepoint

Six Days

Method of measurement

Cheek List APACHE II

2

Description

Physiological indicators

Timepoint

Six Days

Method of measurement

Cheek List

Secondary outcomes

1

Description

Regular meeting

Timepoint

Fifteen minutes before the meeting, During the half-hour meeting and fifteen minutes after meeting for six days

Method of measurement

Questionnaire

Intervention groups

1

Description

The presence of family members (to have Strong emotional relationship with a person hospitalized) In intensive care units two times per day in the first six Admission Besides patient and doing Trained health care activities

Category

Other

2

Description

The control group does not intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Hospital Ghaen

Full name of responsible person

Mohammad Reza Jani

Street address

Shohada Hospital, Cement City, St Healing, Ghaen
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2

Recruitment center

Name of recruitment center

Hospital 22 Bahman Gonabad

Full name of responsible person

Mohammad Reza Jani

Street address

Hospital 22 Gonabad, Naser Khosrow Street, Gonabad,
Khorasan Razavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Medical University
Gonabad

Full name of responsible person

Ali Akrami

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Vice chancellor for Education and Research of Medical
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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, Medical University Gonabad

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

Medical University Gonabad

Full name of responsible person

Mohammad Reza Jani

Position

MS Student Care Nursing

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

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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