Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Sep 2026

The effect of increasing visitation time on physiological parameters,pain and level of consciousness in patients hospitalized in the ICU

Protocol summary

Summary
This is a single blind clinical trial to evaluate the effect of increased visitation time on physiological parameters,pain and level of consciousness in patients hospitalized in the ICU. Sixty patients will be selected according to inclusion and exclusion criteria with with available sampling and will be randomly divided into intervention (Visiting has been done for 10 minutes 3 times a day (9, 12,15 o'clock) and control groups (10 minutes once a day (15 o'clock)). then patients' physiological parameters (blood pressure systolic and diastolic mean arterial pressure, pulse, temperature, respiratory rate, arterial oxygen saturation, pain and level of consciousness), will be comparison before, during, and after 10 and 30 minutes after visitation.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT2014052617873N1**
Registration date: **2015-03-11, 1393/12/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2015-03-11, 1393/12/20

Registrant information
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Recruitment status
Recruitment complete

Funding source
Research Deputy of Arak University of Medical Sciences

Expected recruitment start date
2014-05-22, 1393/03/01
Expected recruitment end date
2014-08-23, 1393/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of increasing visitation time on physiological parameters,pain and level of consciousness in patients hospitalized in the ICU

Public title
The effect of increasing visitation time in patient hospitalized in the critical care unit

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:patient hospitalized in the ICU with level of consciousness more than seven, at least past 24 hours from admission, patients age range of 18 to 70 years old, not complete isolated,receiving narcotics and sedatives at least six hours previously. Exclusion criteria:If participate in a study that interfere with our study, any condition that requires emergency medical and nursing intervention and receive medications such as dopamine, dobutamine and nitroglycerin during the study.

Age
From **17 years** old to **69 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)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Arak University of Medical Sciences
Street address
Faculty of Nursing and Midwifery, Arak University of Medical Sciences, Sardasht,
City
Arak
Postal code
Approval date
2014-03-12, 1392/12/21
Ethics committee reference number
93-164-2

Health conditions studied

1

Description of health condition studied
Physiologic parameters, pain and level of consciousness
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Physiologic parameters
Timepoint
Pre visitation, diring,10 and 30 minute after visitation
Method of measurement
Monitoring devices

2

Description
Level of consciousness
Timepoint
Pre visitation, diring,10 and 30 minute after visitation
Method of measurement
Glasgow Coma Scale

3

Description
Pain
Timepoint
Pre visitation, diring,10 and 30 minute after visitation
Method of measurement
Pain Visible Scale

Secondary outcomes

empty

Intervention groups

1

Description
In intervention group patient will be met by family members for 10 minutes 3 times a day (9, 12,15 o’clock)
Category
Behavior

2

Description
In control group patients will be met for 10 minutes once a day (9 o’clock).
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak University of Medical Sciences
Full name of responsible person
Parvaneh asgari
Street address
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr.rafei

Street address
Arak; Rahahan Sq;Alamolhoda St; Arak University of Medical Sciences
City
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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
Arak 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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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