

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Comparison of physical restraint application and family bedside on blood cortisol in patients hospitalized in intensive care units.

Protocol summary

Summary

We will compare the impact of two methods; Routine Physical restraint and attendance of patients on patient's blood cortisol levels in Intensive Care Units. 18 Patients who will physically restrain routinely by nurses and more than three days are in the ICU will randomly divide into two groups. Study will carry out on two consecutive days. In group 1, in the first day, 30 min after the release of restraint, patients will then physically restrain for 1 hour. In second day of study we will use from attendance instead of restraint in the same manner. In group 2, we will study about the impact of attendance on blood cortisol levels in the first day and then about the physical restraint in second day. The blood samples should take before the intervention in first day and after the intervention in first and second days in two groups. We will analyze the results of two groups. Any severe change in the condition of the patient during two days of therapy and during any invasive procedure, causing the withdrawal of the patient from the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013110415271N1**
Registration date: **2013-12-03, 1392/09/12**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-12-03, 1392/09/12

Registrant information

Name

Mojdeh Navidhamidi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4314

Email address

m-navid@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Student dissertations and academic plans

Expected recruitment start date

2013-12-06, 1392/09/15

Expected recruitment end date

2014-01-30, 1392/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of physical restraint application and family bedside on blood cortisol in patients hospitalized in intensive care units.

Public title

Care of patient hospitalized in critical care unit

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: All patients were hospitalized for more than three days in the ICU during the study;The patients should not given any corticosteroids, anti-seizure drugs and insulin during study .The patients should not suffer from sepsis (widespread infection of the blood); The patients should take stable blood electrolytes. Exclusion criteria: Patient's death;any Severe change in the condition of the patient during the two days of study; Use

of any invasive procedure during the study; Release of restraint by employees; Legal guardian dissatisfaction to the continuation of the study

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **18**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran university of medical sciences and health services

Street address

Research Council of Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2013-09-23, 1392/07/01

Ethics committee reference number

14 / 130 /92/5

Health conditions studied

1

Description of health condition studied

Stress

ICD-10 code

Z74.0

ICD-10 code description

Need for assistance due to reduced mobility

Primary outcomes

1

Description

Cortisol

Timepoint

Before intervention, one hour after intervention

Method of measurement

Elisa Method

Secondary outcomes

empty

Intervention groups

1

Description

Control Group:

Category

Prevention

2

Description

Intervention Group: In the presence of researcher, patient should be free of physical restraint for 30 min and then attendance of patient will be ready beside the patient. After then we will take the blood sampling from the patient and the cortisol level will measure on a laboratory.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Masood Ahmadpoor

Street address

Jeneral Icu, Valiasr hospital

City

Tehran

2

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Fatemeh Fathi

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ms Anoosheh

Street address

Research Council of Tehran University of Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences, School of Nursing and Midwifery

Full name of responsible person

Dr. Mojdeh Navid hamidi

Position

Assistant Prof of Phisiology, Head of Medical Basic Sciences

Other areas of specialty/work

Street address

Tohid Square, School of Nursing and Midwifery

City

Tehran

Postal code

Phone

+98 21 6105 4314

Fax

Email

m-navid@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mojdeh Navidhamidi

Position

Assistant Prof , Ph.D. of Physiology

Other areas of specialty/work

Street address

Tohid Square, School of Nursing and Midwifery, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 6105 4314

Fax

Email

m-navid@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mojdeh Navidhamidi

Position

Assistant Prof. Ph.D. of Physiology

Other areas of specialty/work

Street address

Tohid Square, School of Nursing and Midwifery, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 6105 4314

Fax

Email

m-navid@tums.ac.ir

Web page address

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