

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Effect of progesterone administration on outcome of patients with diffuse axonal injury due to severe head trauma

Protocol summary

Summary

From 76 male patients above 15 year-old with multiple trauma and diagnosis of DAI who are admitted at hospital with GCS score < 8 within first 6 hours of their trauma we select two groups consist of 33 patients randomly and administer medroxi progesterone tablet (1mg/kg or 30 mg/BID) via NG tube for 5 days to one group, the control group don't take this drug. Finally the GCS and GOS of them will be checked and compared till the time of discharge. Only the nurses giving the drug to patients are aware of those taking the drug so the study is single-blinded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011225230N1**
Registration date: **2010-12-23, 1389/10/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-12-23, 1389/10/02

Registrant information

Name

Moslem Shakery

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-08-23, 1390/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of progesterone administration on outcome of patients with diffuse axonal injury due to severe head trauma

Public title

Effect of progesterone administration on outcome of patients with diffuse axonal injury due to severe head trauma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: men with a diagnosis of Diffuse Axonal Injury and GCS<8 Exclusion criteria: female sex and male under 15 years old

Age

From **15 years** old to **100 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

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

Ethics committee of Tabriz University of Medical Sciences

Street address

neurosurgery ward, Imam Reza hospital, golgasht ave, Tabriz, Iran.

City

Tabriz

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

5/4/5713

Health conditions studied

1

Description of health condition studied

diffuse axonal injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse brain injury

Primary outcomes

1

Description

GCS or level of consciousness

Timepoint

daily

Method of measurement

3-15

Secondary outcomes

1

Description

GOS

Timepoint

when patient discharged

Method of measurement

moderate disability good Recovery , severe disability , vegetative, death

Intervention groups

1

Description

Intervention groups: male patients above 15 year-old with multiple trauma and diagnosis of DAI who are admitted at hospital with GCS score < 8 within first 6 hours of their trauma this group consist of patients randomly and administer medroxi progesterone tablet (1mg/kg or 30 mg/BID) via NG tube for 5 day .

Category

Treatment - Drugs

2

Description

control groups: did not receive progesterone

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Moslem Shakery

Street address

Vice chancellor for research, Tabriz University of Medical Sciences , Golgasht Ave,

City

Tabriz

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, Tabriz 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

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Email
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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