

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Evaluation of improved outcomes from the administration of progesterone after severe traumatic brain injury

Protocol summary

Summary

This study is carried out as a randomized clinical trial (Prospective randomized clinical trial). People who are eligible for inclusion, in the first 8 hours after traumatic brain injury, are classified accidentally In to intervention group and the control group. For patients in the intervention group administrated 1 mg / kg every 12 hours for up to 3 days of progesterone as IM injection and not be prescribed any drug for patient in the control group GOS and MFIM levels in patients, one and three months after it, is reviewed and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012080810536N1**
Registration date: **2012-12-01, 1391/09/11**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-01, 1391/09/11

Registrant information

Name

Majid Kalbasi

Name of organization / entity

Islamic azad university najaf abad

Country

Iran (Islamic Republic of)

Phone

+98 31 2521 6952

Email address

dr-kalbasi@smd.iaun.ac.ir

Recruitment status

Recruitment complete

Funding source

Islamic Azad University Najaf Abad

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of improved outcomes from the administration of progesterone after severe traumatic brain injury

Public title

Effect of progesterone on head injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: all male and female patients 18 years and more with admission GCS 8-4 during the first 8 hours on a voluntary and informed consent Exclusion criteria: injuries incompatible with life; bilateral dilated and no response to light pupils; spinal cord injury with neurological deficit; cardiopulmonary arrest; status epilepticus on arrival; initial systolic blood pressure less than 90; initial oxygen saturation less than 90%; pregnant women; any known previous or current cancer; known sensitivity to progesterone; known Coagulation disorders and lack of desire to continue research.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 48

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

clinicaltrials.gov

Secondary trial Id

NCT01143064

Registration date

2010-06-10, 1389/03/20

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Isfahan, Azadi sq , Isfahan University of Medical Sciences

City

Isfahan

Postal code

Approval date

2012-10-22, 1391/08/01

Ethics committee reference number

491007

Health conditions studied

1

Description of health condition studied

Head injury

ICD-10 code

S06

ICD-10 code description

Intracranial injury

Primary outcomes

1

Description

Glasgow Outcome Score

Timepoint

One and three months after intervention

Method of measurement

GOS

2

Description

Functional Independence Measure

Timepoint

One and three months after intervention

Method of measurement

FIM

Secondary outcomes

empty

Intervention groups

1

Description

For patients in the intervention group administrated 1 mg / kg every 12 hours for up to 3 days of progesterone as IM injection.

Category

Treatment - Drugs

2

Description

For patients in control group, progesterone not will be administrated. Assessment of patients carry out according to GOS and FIM, one and three months after third day after admidet in hospital.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Sharaiti hospital

Full name of responsible person

Majid Kalbasi

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University Najaf Abad

Full name of responsible person

Kamran Tavakol

Street address

Islamic azad university najaf ababd-medicine faculty

City

Najaf abad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University Najaf Abad

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**

Islamic Azad University Najaf Abad

Full name of responsible person

Majid Kalbasi

Position

Student of Medicine, Internship

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

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Assistant Professor of Neurosurgery

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Fax**Email****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*