

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Evaluation of neuroprotective effect of progesteron in moderate to severe traumatic brain injury

Protocol summary

Summary

96 patients who have inclusion criteria;The patients who suffered from severe traumatic brain injury that reffered to emergency departemant; They have Glasscow coma scale 4 to 8; They were not undergo surgery for any reason; They were not suffered from cardiopulmonary arrest will be selected then primary demographic information of patients include age, sex and time of trauma was questioned and recorded. Patient will be subgrouped in placebo and treatment group incidentally. In treatment group progesteron will be administrated intravenously with 1 milligram per kilogram per 12 hours for 5 days. The information about level of conscious at arrival, sixth day,third week, third mounth was evaluated. Then the time of admision in intensive care unit, Glasscow coma scale and Glasscow outcome scale in control and treatment group will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014123020487N1**
Registration date: **2015-06-10, 1394/03/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-10, 1394/03/20

Registrant information

Name

Mohamad Ardeshiri

Name of organization / entity

Ahvaz Jundi Shapour University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3032

Email address

ardeshiri.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of neuroprotective effect of progesteron in moderate to severe traumatic brain injury

Public title

Progesteron in treatment traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The patients who suffered from sever traumatic brain injury that reffered to emergency departemant; They have Glasscow coma scale 4 to 8; They were not undergo surgery for any reason; They were not suffered from cardiopulmonary arrest Exclusion criteria: The patient who that undergo surgery for any reason; females who are pregnant

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 96

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Ahvaz Jundi Shapour University of Medical Science, Golestan area, Ahvaz, Khuzestan, Iran

City

Ahvaz

Postal code

15794 - 61357

Approval date

2015-03-07, 1393/12/16

Ethics committee reference number

ajums.REC.1393.416

Health conditions studied

1

Description of health condition studied

Diffuse Brain Injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse Brain Injury

Primary outcomes

1

Description

Average Glosscow coma scale

Timepoint

preadmission, 6 th day, 3 month after admission

Method of measurement

Glosscow coma scale

Secondary outcomes

1

Description

Average Glosscow outcome scale

Timepoint

At discharge time, 3 month later

Method of measurement

Glasscow outcome scale

2

Description

Duration of admission in intensive care unit before and after treatment in control and treatment group

Timepoint

In admission period

Method of measurement

Number of admission days

Intervention groups

1

Description

Intervention group: patients in treatment group was given intravenous progesteron 1 milligram per kilogram per 12 hours for 5 days.

Category

Treatment - Drugs

2

Description

Control group:Then patients in Control group will give intravenous injectionable serum every 12 hour for 5 day

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital of Ahvaz

Full name of responsible person

Dr mohamad ardeshiri

Street address

Golestan hospital,University of Medical Science, Golestan area, Ahvaz, Khuzestan, Iran

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundi Shapour University of Medical Science

Full name of responsible person

Dr . nader saki

Street address

Vice of reasearch and technology, Ahvaz Jundi
Shapour University of Medical Science, Golestan area,
Ahvaz, Khuzestan, Iran

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jundi Shapour University of Medical Science

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

Ahvaz Jundi Shapour University of Medical Science

Full name of responsible person

Dr mohamad ardeshiri

Position

Resident of neurosurgery-MD

Other areas of specialty/work

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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