Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of neuroprotective effect of progestron 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 progestron 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)
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+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 progestron in moderate to severe traumatic brain injury

Public title

Progestron 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
preaddmition, 6 th day, 3 month after addmition
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 progestron 1 milligram per kilogam 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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Person responsible for updating data

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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