Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of estrogen on recovery of prognosis in patient with diffuse axonal injury due to severe traumatic brain injury in men 15 to 70 years old

Protocol summary

Summary

This study will examine the effects of estrogen in the prognosis of men 15 to 70 years old with diffuse axonal injury due to severe brain trauma. This is a randomized; single-blind; without placebo-controlled; single center study. Two parallel groups consist of 20 as case and 20 as control group randomly (crossed intricately) with diffuse axonal injury due to severe brain trauma with equal and less than 8 GCS whom admitted less than 8 hours after trauma in Tabriz emam reza hospital were taken. Patients with refractory seizure; history of deep vein thrombosis; any history of head trauma; cerebrovascular procedures; ischemic and hemorrhagic lesions in the brain; people prone to pulmonary thromboembolism and deep vein thrombosis were excluded. Patients in case group have been under medical treatment after the time of admission with conjugated estrogen (8 micrograms per kilogram for 3 days). Patients in the control group wouldn't receive another drug. Two groups will be compared of GCS at admission and discharge; GCS of discharge and 3 months later using a questionnaire.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2014091919227N1**
Registration date: **2016-01-17, 1394/10/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-01-17, 1394/10/27

Registrant information

Name

keyvan Aalizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of estrogen on recovery of prognosis in patient with diffuse axonal injury due to severe traumatic brain injury in men 15 to 70 years old

Public title

Effects of estrogen on prognosis of patient with diffuse axonal injury due to severe traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Men 15 to 70 years; Diffuse axonal injury diagnosis; GCS less than or equal to 8; Hospitalization in less than 8 hours of after trauma; Having informed consent to participate in the study; Lack of talent to thromboembolism. Exclusion criteria: Sex woman; Patients with refractory seizure; History of deep vein thrombosis or infection; Any history of head trauma; Any history of brain procedure; History of ischemic lesions and hemorrhagic stroke; People prone to pulmonary thromboembolism and deep vein thrombosis; (a) smoking; (b) a family history of deep vein thrombosis and pulmonary thromboembolism; (c) heart failure; (d) inflammatory bowel disease (ulcerative colitis); (e) a history of cancer; (f) hereditary disorders are prone to blood clots

Age
From **14 years** old to **69 years** old

Gender
Male

Phase
2

Groups that have been masked
No information

Sample size
Target sample size:

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Classification of patients will be crossed intricately.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Neurosurgery department office, Imam Reza Hospital, Daneshgah Avenue, Tabriz, East Azarbayejan, Iran

City
Tabriz

Postal code
5166614756

Approval date
2014-04-28, 1393/02/08

Ethics committee reference number
9357

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
level of consciousness

Timepoint
Admission time, discharge time and three months after discharge

Method of measurement
Glasgow coma scale

Secondary outcomes

empty

Intervention groups

1

Description
8 micrograms of oral conjugated estrogen tablets per kg body weight, once a day until 3 days for the intervention group

Category
Treatment - Drugs

2

Description
Not prescribed any medication for control group.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Education, research and treatment center of Imam Reza (AS)

Full name of responsible person
Keyvan Aalizadeh,MD

Street address
Imam Reza Hospital, Daneshgah Avenue, Tabriz, East Azarbayejan, Iran

City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chanscellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Hassan Soleimanpour
Street address
Vice chanscellor for research, Tabriz University of Medical Sciences, Tabriz University of Medical Sciences, , Daneshgah Avenue, Tabriz, East Azarbayjan, Iran
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chanscellor 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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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