

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 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)

Phone

+98 41 1331 6956

Email address

mreza@tbzmed.ac.ir

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 chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Hassan Soleimanpour

Street address

Vice chancellor 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 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**

Tabriz University of Medical Sciences

Full name of responsible person

Keyvan Aalizadeh, MD

Position

Resident of Neurosurgery

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

Neurosurgery Department Office, Imam Reza Hospital, Daneshgah Avenue, Tabriz, East Azarbayejan, Iran

City

Tabriz

Postal code

5166614756

Phone

+98 41 3334 0830

Fax

+98 41 3334 0830

Email

aalizadehkeyvan@ymail.com; mreza@tbzmed.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Javad Agazadeh, MD

Position

Associate Professor of Neurosurgery

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

Neurosurgery Department Office, Imam Reza Hospital, Daneshgah Avenue, Tabriz, East Azarbayejan, Iran

City

Tabriz

Postal code

5166614756

Phone

+98 41 3334 0830

Fax

+98 41 3334 0830

Email

javadagazadeh@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Keyvan Aalizadeh, MD

Position

Resident of Neurosurgery

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

Neurosurgery Department Office, Imam Reza Hospital, Daneshgah Avenue, Tabriz, East Azarbayejan, Iran

City

Tabriz

Postal code

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Phone

+98 41 3334 0830

Fax

+98 41 3334 0830

Email

aalizadehkeyvan@ymail.com; mreza@tbzmed.ac.ir

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