

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the efficacy and probable mechanism of estrogen and progesterone on the complications of moderate and severe diffuse traumatic brain injury in patients admitted in Kerman Shahid Bahonar Hospital: a clinical trial

Protocol summary

Summary

Traumatic brain injury is an important public health problem and a leading cause of injury-related death and disability. Inflammatory and anti-apoptotic effects and significantly reduces secondary damage. Although pre-clinical studies show the advantage of progesterone, and there are positive results two human clinical trials, more clinical trials are needed to confirm the use of progesterone in acute traumatic brain injury. Taken the neuroprotective potential benefits of estrogen therapy, time is for controlled clinical trials of estrogen therapy in traumatic brain injury. Therefore, in this study, the probable efficacy and potential mechanism of estrogen and progesterone in reduction of brain damage in patients with moderate and severe traumatic brain injury, 18 to 60 years old admitted in Kerman Shahid Bahonar Hospital, in a Randomized, double-blind, placebo-controlled clinical trial are tested. In this study inclusion criteria: diffuse TBI; being male; having age between 18 to 60 years of age and severity of moderate to severe brain injury with GCS (Glasgow Coma Scale) (with grades 3-8 as severe and 9-12 as moderate). Exclusion criteria: patients with blunt head trauma; damage with unknown time; entering the hospital with damage time more than 4 hours; severe hypothermia (temperature less than 28 ° C); age less than 18 years and more than 60 years; SCI, patients who are candidates for craniotomy; diseases related to the immune system, gastrointestinal, oncology, infectious diseases, and other associated trauma are. Patients are divided randomly 3 groups; Control group: in this group, only routine and standard treatment is done. Progesterone group: in addition to routine and standard treatment, progesterone dose 1 mg /kg within 4 hours of brain damage is administered intramuscularly, and then this dose is repeated every 12 hours for 5 consecutive

days. Estrogen group: in addition to routine and standard treatment, estrogen dose 1/25 mg within 4 hours of brain damage is administered oral, and then this dose is repeated everyday for 5 consecutive days. In this study, GOS (Glasgow-Outcome Scale-Extended), FIM (Functional Independence Measure), and CRS-R (coma recovery scale - revised) are measured after resuscitation, time discharge, 3 and 6 months after TBI. Serum inflammatory factors, Serum brain proteins, Serum MDA (Malondialdehyde) Levels, Serum protein carbonyl content, and Serum levels of total antioxidant activity are measured, After resuscitation, 24 hours and 6 days after TBI.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042017356N1**

Registration date: **2014-08-21, 1393/05/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-21, 1393/05/30

Registrant information

Name

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Name of organization / entity

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Recruitment status**Recruitment complete****Funding source**

Kerman Neuroscience Research Center, Research Council of Kerman University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy and probable mechanism of estrogen and progesterone on the complications of moderate and severe diffuse traumatic brain injury in patients admitted in Kerman Shahid Bahrani Hospital: a clinical trial

Public title

Effect of female sex hormones on traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diffuse TBI; being male; having age between 18 to 60 years of age and severity of moderate to severe brain injury with GCS (Glasgow Coma Scale) (with grades 3-8 as severe and 9-12 as moderate).
Exclusion criteria: patients with blunt head trauma; damage with unknown time; entering the hospital with damage time more than 4 hours; severe hypothermia (temperature less than 28 ° C); age less than 18 years and more than 60 years; SCI, patients who are candidates for craniotomy; diseases related to the immune system, gastrointestinal, oncology, infectious diseases, and other associated trauma.

Age

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

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

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**

Research Council of Kerman University of Medical Sciences

Street address

Sina Avenue, Jihad blvd., Somayeh cross

City

Kerman

Postal code**Approval date**

2014-04-13, 1393/01/24

Ethics committee reference number

92/579/5

Health conditions studied**1****Description of health condition studied**

Traumatic brain injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse brain injury

Primary outcomes**1****Description**

GOS (Glasgow-Outcome Scale-Extended)

Timepoint

after resuscitation, time discharge, 3 and 6 months after TBI

Method of measurement

Questionnaire

2**Description**

FIM (Functional Independence Measure)

Timepoint

after resuscitation, time discharge, 3 and 6 months after TBI

Method of measurement

Questionnaire

3**Description**

CRS-R (coma recovery scale - revised)

Timepoint

After resuscitation, time discharge, 3 and 6 months after TBI

Method of measurement

Questionnaire

4**Description**

serum inflammatory factors

Timepoint

After resuscitation, 24 hours and 6 days after TBI

Method of measurement

ELISA

5**Description**

Serum brain proteins

Timepoint

After resuscitation, 24 hours and 6 days after TBI

Method of measurement

ELISA

6**Description**

Serum MDA(Malon dialdeid) Levels

Timepoint

After resuscitation, 24 hours and 6 days after TBI

Method of measurement

Thiobarbituric acid method

7**Description**

Serum protein carbonyl content

Timepoint

After resuscitation, 24 hours and 6 days after TBI

Method of measurement

DNPH(2, 4-D Nytrvfnl hydrazine) method

8**Description**

Serum levels of total antioxidant activity

Timepoint

After resuscitation, 24 hours and 6 days after TBI

Method of measurement

ferric reducing of antioxidants power (FRAP)

Secondary outcomes**1****Description**

mortality

Timepoint

24 hours, and 1, 3 and 6 months after TBI

Method of measurement

number

2**Description**

complications and adverse effects

Timepoint

24 hours, and 1, 3 and 6 months after TBI

Method of measurement

visual

3**Description**

Length of stay

Timepoint

Hospitalization time

Method of measurement

visual

4**Description**

differenace GCS between Admission and discharge times

Timepoint

hospitalization

Method of measurement

visual

Intervention groups**1****Description**

Control group: in this group, only routine and standard treatment is done.

Category

Placebo

2**Description**

Progesterone group: in addition to routine and standard treatment, progesterone dose 1 mg /kg within 4 hours of brain damage is administered intramuscularly, and then this dose is repeated every 12 hours for 5 consecutive days.

Category

Treatment - Drugs

3**Description**

Estrogen group: in addition to routine and standard treatment, estrogen dose 1/25 mg within 4 hours of brain damage is administered oral, and then this dose is repeated everyday for 5 consecutive days.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kerman Shahid Bahonar Hospital

Full name of responsible person

Saeed Karamouzian
Street address
City
Kerman

empty
Country of origin
Type of organization providing the funding
empty

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman Neuroscience Research Center
Full name of responsible person
Dr. Vahid Sheibani
Street address
Sina Avenue, Jahad blvd., somayeh cross
City
Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman Neuroscience Research Center

Proportion provided by this source

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

2

Sponsor

Name of organization / entity
Research Council of Kerman University of Medical Sciences
Full name of responsible person
Dr. Abbass Pardakhti
Street address
Sina Avenue, Jahad Blvd., somayeh cross
City
Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Council of Kerman University of Medical Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

Person responsible for general inquiries

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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