

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Evaluation of improved outcomes from the administration of progesterone after severe traumatic brain injury

#### Protocol summary

##### Summary

This study is carried out as a randomized clinical trial (Prospective randomized clinical trial). People who are eligible for inclusion, in the first 8 hours after traumatic brain injury, are classified accidentally In to intervention group and the control group. For patients in the intervention group administrated 1 mg / kg every 12 hours for up to 3 days of progesterone as IM injection and not be prescribed any drug for patient in the control group GOS and MFIM levels in patients, one and three months after it, is reviewed and compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012080810536N1**  
Registration date: **2012-12-01, 1391/09/11**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-12-01, 1391/09/11

##### Registrant information

##### Name

Majid Kalbasi

##### Name of organization / entity

Islamic azad university najaf abad

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 2521 6952

##### Email address

dr-kalbasi@smd.iaun.ac.ir

##### Recruitment status

Recruitment complete

##### Funding source

Islamic Azad University Najaf Abad

##### Expected recruitment start date

2012-10-22, 1391/08/01

##### Expected recruitment end date

2012-12-21, 1391/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of improved outcomes from the administration of progesterone after severe traumatic brain injury

##### Public title

Effect of progesterone on head injury

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria: all male and female patients 18 years and more with admission GCS 8-4 during the first 8 hours on a voluntary and informed consent Exclusion criteria: injuries incompatible with life; bilateral dilated and no response to light pupils; spinal cord injury with neurological deficit; cardiopulmonary arrest; status epilepticus on arrival; initial systolic blood pressure less than 90; initial oxygen saturation less than 90%; pregnant women; any known previous or current cancer; known sensitivity to progesterone; known Coagulation disorders and lack of desire to continue research.

##### Age

From **18 years** old to **100 years** old

##### Gender

Both

##### Phase

2

## Groups that have been masked

No information

## Sample size

Target sample size: 48

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

### 1

#### Registry name

clinicaltrials.gov

#### Secondary trial Id

NCT01143064

#### Registration date

2010-06-10, 1389/03/20

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Isfahan University of Medical Sciences

##### Street address

Isfahan, Azadi sq , Isfahan University of Medical Sciences

##### City

Isfahan

##### Postal code

#### Approval date

2012-10-22, 1391/08/01

#### Ethics committee reference number

491007

## Health conditions studied

### 1

#### Description of health condition studied

Head injury

#### ICD-10 code

S06

#### ICD-10 code description

Intracranial injury

## Primary outcomes

### 1

#### Description

Glasgow Outcome Score

#### Timepoint

One and three months after intervention

#### Method of measurement

GOS

### 2

#### Description

Functional Independence Measure

#### Timepoint

One and three months after intervention

#### Method of measurement

FIM

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

For patients in the intervention group administrated 1 mg / kg every 12 hours for up to 3 days of progesterone as IM injection.

#### Category

Treatment - Drugs

### 2

#### Description

For patients in control group, progesterone not will be administrated. Assessment of patients carry out according to GOS and FIM, one and three months after third day after admidet in hospital.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ali Sharaiti hospital

##### Full name of responsible person

Majid Kalbasi

##### Street address

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University Najaf Abad

##### Full name of responsible person

Kamran Tavakol

**Street address**

Islamic azad university najaf ababd-medicine faculty

**City**

Najaf abad

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Islamic Azad University Najaf Abad

**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**

Islamic Azad University Najaf Abad

**Full name of responsible person**

Majid Kalbasi

**Position**

Student of Medicine, Internship

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

Chaharbagh bala ave- shariati hospital

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kalbasimajid@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University Najaf Abad

**Full name of responsible person**

Farid Zolfaghari

**Position**

Assistant Professor of Neurosurgery

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Islamic Azad University of Najaf Abad

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Majid Kalbasi

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Student of Medicine, Internship

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

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**Postal code****Phone**

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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*