

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison study the effect of nimodipine, magnesium sulfate and progesterone in the treatment of severe head injury with conventional therapy on reducing mortality rate

Protocol summary

Summary

The aim of the study: Comparison study the effect of nimodipine, magnesium sulfate and progesterone in the treatment of severe head injury with conventional therapy on reducing mortality rate study design: Randomized, Non-blinded, Non-placebo-controlled, Single-center, parallel Study population: Inclusion criteria: All patients with head injury and with Glasgow Coma Scale lower than 8 who will refers to Emergency ward of Besat Hospital in the 1392 year. Exclusion criteria: Pregnant woman Any type of brain surgery instability from surgical aspect Using estrogen and progesterone in the last 30 days Brain death Systolic blood pressure below 90 Patients with kidney problems Sample volume: One hundred and twenty four patients in the two randomized group by using blocks. Interventions and the timing: Control group: They will be treat as routine: 1) Anti-seizure drugs, 2) Serum therapy, 3)Dexamethasone if needed 4), Doing necessary action according to the clinical situation. Cases group: In addition to routine treatments: These patients will receive progesterone based on a mg per kg(s) initially and then the same amount every 12 hours for 5 days, nimodipine 60 milli grams every 4 hours for 21 days, and 5 grams of magnesium sulfate initially and than 2 and a half grams daily for 5 days. Primary outcome: Reduction in mortality in cases group compared to the control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210229534N2**
Registration date: **2014-01-18, 1392/10/28**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-18, 1392/10/28

Registrant information

Name

Esmaeil Gol Mahmoudi

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences-vice chancellor for research

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison study the effect of nimodipine, magnesium sulfate and progesterone in the treatment of severe head injury with conventional therapy on reducing mortality rate

Public title

Studying the effect of nimodipin, progesterone and magnesium sulfate in the treatment of severe head injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients with head injury and with Glasgow Coma Scale lower than 8 who will refer to Emergency ward of Besat Hospital in the 1392 year.

Exclusion criteria: Pregnant woman; Any type of brain surgery; Instability from surgical aspect; Using estrogen and progesterone in the last 30 days; Brain death; Systolic blood pressure below 90; Patients with kidney problems

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamedan University of Medical Sciences

Street address

Mahdiye Street, Hamedan University Of Medical Sciences

City

Hamedan

Postal code

6661737343

Approval date

2012-06-26, 1391/04/06

Ethics committee reference number

16/35/9/1117/پ/د

Health conditions studied

1

Description of health condition studied

Head Trauma

ICD-10 code

S09

ICD-10 code description

Other and unspecified injuries of head

Primary outcomes

1

Description

Patient's death

Timepoint

During 6 Month

Method of measurement

Follow the patient

Secondary outcomes

empty

Intervention groups

1

Description

progesterone based on a mg per kg(s) initially and then the same amount every 12 hours for 5 days Intervention group

Category

Treatment - Drugs

2

Description

nimodipine 60 milli grams every 4 hours for 21 days Intervention group

Category

Treatment - Drugs

3

Description

5 grams of magnesium sulfate initially and than 2 and a half grams daily for 5 days Intervention group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Ali Abdoli

Street address

Besat Hospital. Ayatollah Motahari Blvd

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Hamadan

Web page address

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Hamadan Univesity of Medical Science,Hamedan
University of Medical Sciences-vice chancellor for rese**Full name of responsible person**

Dr.Bashirian

Street addressMahdiye Street, Hamedan University Of Medical
Sciences**City**

Hamadan

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

Yes

Title of funding sourceHamadan Univesity of Medical Science,Hamedan
University of Medical Sciences-vice chancellor for rese**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**

Hamadan University of Medical Science

Full name of responsible person

Sepideh Sohrabi

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Medical student

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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