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 Glascow 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
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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 Glascow 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
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/د/پ

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. Ayatolah Motahari Blvd
City
Hamadan

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 address
Mahdiye 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 source
Hamadan 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
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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