

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Effect of hyperoxia with FIO₂ 80% in comparison with FIO₂ 50% on Glasgow Outcome Scale, Barthel Index and Modified Ranking Scale in patients with severe traumatic brain injury: a double blinded randomized clinical trial

Protocol summary

Summary

Objective: To assess the effect of hyperoxia with FIO₂ 80% in comparison with FIO₂ 50% on Glasgow Outcome Scale (GOS) and Barthel Index and Modified Rankin Scale in patients with severe traumatic brain injury Design: A double blinded randomized controlled trial. Setting: The eligible patients of 15 to 65 years of age who will be admitted to intensive care unit (ICU) of Besat hospital during 2013 due to head trauma. Inclusion criteria: (a) age of 4-12 years of both genders; (b) no indication of brain surgery; (c) not admitted later than 6 hours; and (d) stable hemodynamic status. Exclusion criteria: (a) simultaneous trauma to vertebral column or other parts of the body; (b) having chronic diseases such as diabetes, chronic pulmonary disease, cardiovascular diseases, or cancer; (c) presence of hypoxia or hypotension before intervention; (d) being undergone cardiopulmonary resuscitation; (e) needing entropic or antihypertensive medications. Intervention: using 80% oxygen once for 6 hours using ventilator Control: using 50% oxygen once for 6 hours using ventilator Primary outcome 1: measuring Glasgow Outcome Scale (GOS) at discharge and 6 months later Primary outcome 2: measuring Barthel Index at discharge and 6 months later Primary outcome 3: measuring Modified Ranking Scale at discharge and 6 months later Secondary outcome: measuring the duration of hospitalization in intensive care unit (ICU) and neurosurgery ward

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201303209014N17**
Registration date: **2013-11-29, 1392/09/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-11-29, 1392/09/08

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

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Phone

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-05-22, 1393/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of hyperoxia with FIO₂ 80% in comparison with FIO₂ 50% on Glasgow Outcome Scale, Barthel Index and Modified Ranking Scale in patients with severe traumatic

brain injury: a double blinded randomized clinical trial

Public title

Effect of hyperoxia with FIO₂ 80% in comparison with FIO₂ 50% on Glasgow Outcome Scale, Barthel Index and Modified Ranking Scale in patients with severe traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) age of 4-12 years of both genders; (b) no indication of brain surgery; (c) not admitted later than 6 hours; and (d) stable hemodynamic status.

Exclusion criteria: (a) simultaneous trauma to vertebral column or other parts of the body; (b) having chronic diseases such as diabetes, chronic pulmonary diseases, cardiovascular diseases, or cancer; (c) presence of hypoxia or hypotension before intervention; (d) being undergone cardiopulmonary resuscitation; (e) needing entropic or antihypertensive medications.

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **68**

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

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave. Hamadan

City

Hamadan

Postal code

6517838695

Approval date

2013-10-29, 1392/08/07

Ethics committee reference number

D/P/16/35/9/2417

Health conditions studied

1

Description of health condition studied

Head trauma

ICD-10 code

S04

ICD-10 code description

Injury of cranial nerves

Primary outcomes

1

Description

Neurological function

Timepoint

At discharge and 6 months later

Method of measurement

Glasgow Outcome Scale (GOS)

2

Description

Neurological function

Timepoint

At discharge and 6 months later

Method of measurement

Barthel Index

3

Description

Neurological function

Timepoint

At discharge and 6 months later

Method of measurement

Modified Ranking Scale

Secondary outcomes

1

Description

Duration of hospitalization in intensive care unit (ICU) and neurosurgery ward

Timepoint

At discharge

Method of measurement

Medical record

Intervention groups

1

Description

Using 80% oxygen once for 6 hours using ventilator

Category

Treatment - Other

2

Description

Using 50% oxygen once for 6 hours using ventilator

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Dr Abbas Taher

Street address

Besat Hospital, Imam Hossein Square

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Vice chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave.

City

Hamadan

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 the Technology, Hamadan
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

Besat Hospital

Full name of responsible person

Dr Abbas Taher

Position

Resident of Anesthesia

Other areas of specialty/work

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Person responsible for scientific inquiries

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Web page address

Person responsible for updating data

Contact

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