

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Effect of high percent oxygen therapy in compared without oxygen therapy on rehabilitation in the first 12 hours of admission in patients with stroke: a randomized clinical trial

#### Protocol summary

##### Summary

Objective: To assess the effect of high percent oxygen therapy on rehabilitation in the first 12 hours of admission in stroke patients Design: Randomized controlled trial. Setting: The eligible patients with stroke who will refer to neurology ward of Farshchian hospital in 2012. Inclusion criteria: (a) Age greater than 40 and lesser than 70 years; (b) patients who have GCS greater than 12 and patients that have only brain damage also their airway protective reflexes are normal; (c) The patients that their brain CT scans show pure ischemic and hemorrhagic stroke without need to surgery; (d) The patients that do not have acute subdural hematoma and cerebellar hemorrhage; (e) Elapsed time from accident to starting treatment is less than 12 hours; (f) Patients who are in hemodynamically stable condition and their blood pressure is less than 170/90. Exclusion criteria: (a) patients who have underlying cardiovascular disease, diabetes mellitus, renal failure; (b) Patients who need tracheal intubation at the time of hospital admission; (c) Patients with blood pressure less than 90/60; (d) having documented hypoxia; (e) Patients who had successful CPR; (f) Patients who have history of previous stroke. Intervention: 26 patients will receive 50% oxygen in the first 12 hours of admission. Control: 26 patients will receive routine medications without oxygen. Primary outcome: Good recovery and less number of complications in the first day of admission, before discharge, and six months after discharge using ranking scale and Barthel index

#### General information

##### Acronym

GCS: Glasgow coma scale

##### IRCT registration information

IRCT registration number: **IRCT201212199647N2**

Registration date: **2013-11-03, 1392/08/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-11-03, 1392/08/12

##### Registrant information

###### Name

Abbas Taher

###### Name of organization / entity

Hamadan Medical Science University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1264 0063

###### Email address

a.taher@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for Research and Technology Hamadan University of Medical Sciences

##### Expected recruitment start date

2012-04-20, 1391/02/01

##### Expected recruitment end date

2013-02-19, 1391/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of high percent oxygen therapy in compared

without oxygen therapy on rehabilitation in the first 12 hours of admission in patients with stroke: a randomized clinical trial

### Public title

Effect of high percent oxygen therapy in compared without oxygen therapy on rehabilitation in the first 12 hours of admission in patients with stroke

### Purpose

Treatment

### Inclusion/Exclusion criteria

Inclusion criteria: (a) Age greater than 40 and lesser than 70 years; (b) patients who have GCS greater than 12 and patients that have only brain damage also their airway protective reflexes are normal; (c) The patients that their brain CT scans show pure ischemic and hemorrhagic stroke without need to surgery; (d) The patients that do not have acute subdural hematoma and cerebellar hemorrhage; (e) Elapsed time from accident to starting treatment is less than 12 hours; (f) Patients who are in hemodynamically stable condition and their blood pressure is less than 170/90. Exclusion criteria: (a) patients who have underlying cardiovascular disease, diabetes mellitus, renal failure; (b) Patients who need tracheal intubation at the time of hospital admission; (c) Patients with blood pressure less than 90/60; (d) having documented hypoxia; (e) Patients who had successful CPR; (f) Patients who have history of previous stroke.

### Age

From **40 years** old to **70 years** old

### Gender

Both

### Phase

2

### Groups that have been masked

*No information*

### Sample size

Target sample size: **52**

### 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

Regional Ethics Committee, Hamadan university of medical sciences

### Street address

Hamadan university of medical science, Shahid Fahmide Street

### City

Hamadan

### Postal code

### Approval date

2010-08-20, 1389/05/29

### Ethics committee reference number

D/T/16/35/9/4582

## Health conditions studied

### 1

#### Description of health condition studied

haemorrhagic or ischemic stroke

#### ICD-10 code

I64

#### ICD-10 code description

Stroke, not specified as haemorrhage or infarction

## Primary outcomes

### 1

#### Description

Good recovery and less complication

#### Timepoint

First day of admission, before discharge, six months after discharge

#### Method of measurement

Ranking scale, Barthel index

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: will receive 50% oxygen in the first 12 hours of admission

#### Category

Treatment - Drugs

### 2

#### Description

Control group: will receive routine medications without oxygen

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Farshchian hospital Hamadan Iran

**Full name of responsible person**

abbas taher MD,anesthetist,fellowship of critical care medicine

**Street address**

Besat hospital, department of anesthesia and critical care medicine, hamedan, Iran

**City**

Hamadan

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vic-chancellor of research and Technology, Hamadan medical university

**Full name of responsible person**

Ahmad Tavilani

**Street address**

Hamadan University of medical science, Sahid Fahmide Street

**City**

Hamedan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vic-chancellor of research and Technology, Hamadan medical university

**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**

Anesthesia and intensive care department

**Full name of responsible person**

Abbas Taher

**Position**

MD,Anesthetist ,Fellowship Of Critical Care Medicine,Assistant Professor

**Other areas of specialty/work**

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a.taher@umsha.ac.ir; t\_anesthesia@yahoo.com

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Anesthesia and intensive care department

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**Other areas of specialty/work**

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**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*