

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### Evaluation of zolpidem effect on level of consciousness and regional brain perfusion in patients with vegetative state due to trauma

#### Protocol summary

##### Study aim

comparison of the results of Glasscow outcom scale (GOSE) before and 2 weeks after zolpidem consumption  
comparison of the quantitative and qualitative visual results of regional brain perfusion in Single-photon emission computed tomography (SPECT) before and 2 weeks after zolpidem consumption

##### Design

all vegetative patients for 4-8 months after TBI selected consequently from traumatic brain injury database. All patients will be assessed neurologically by a neurosurgeon according to GOSE scaling. Then, patients will be referred to nuclear medicine department for baseline brain perfusion SPECT scan with 99mTc-ECD. After SPECT, Zolpidem 10mg orally BID will be started. After 2 weeks, GOSE and brain perfusion SPECT will be repeated for evaluation of response to treatment 1 hour after oral administration of 10 mg zolpidem. The results of clinical and imaging data before and two weeks after administration of zolpidem will be recorded and analyzed statistically

##### Settings and conduct

vegetative patients selected consequently from traumatic brain injury database of shiraz trauma center (no blinding or randomization)

##### Participants/Inclusion and exclusion criteria

main inclusion criteria: being in vegetative state due to trauma for more than 4-8 months, in a medically stable condition  
main exclusion: allergy to zolpidem

##### Intervention groups

Zolpidem 10mg orally BID for 2 week

##### Main outcome variables

GOSE (Glasgow outcome scale extended), SPECT quantitative reading and visual findings.

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20130310012776N5**

Registration date: **2019-03-10, 1397/12/19**

Registration timing: **retrospective**

Last update: **2019-03-10, 1397/12/19**

Update count: **0**

#### Registration date

2019-03-10, 1397/12/19

#### Registrant information

##### Name

Hosseinali Khalili

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3625 4206

##### Email address

khalili\_h@sums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2018-05-22, 1397/03/01

#### Expected recruitment end date

2018-11-22, 1397/09/01

#### Actual recruitment start date

2018-05-22, 1397/03/01

#### Actual recruitment end date

2018-11-22, 1397/09/01

#### Trial completion date

2018-12-22, 1397/10/01

#### Scientific title

Evaluation of zolpidem effect on level of consciousness and regional brain perfusion in patients with vegetative state due to trauma

**Public title**

Zolpidem trial in traumatic brain injury

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

being in vegetative state due to trauma for more than 4-8 months, in a medically stable condition no severe complications or other comorbidities in addition to brain damage good nutritional status (BMI>18 kg/m2) accepting to participate in the study by patients' family or guardian

**Exclusion criteria:**

Allergic reaction to zolpidem Indication for any additional surgical or medical intervention during zolpidem treatment poor cooperation for SPECT imaging

**Age**

From **15 years** old to **60 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **33**

Actual sample size reached: **12**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Emtiaz hospital, Chamran Blvd, Shiraz, Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

7194815711

**Approval date**

2018-05-03, 1397/02/13

**Ethics committee reference number**

IR.SUMS.MED.REC.1397.080

**Health conditions studied****1****Description of health condition studied**

Vegetative life after traumatic brain injury

**ICD-10 code**

S06

**ICD-10 code description**

Intracranial injury

**Primary outcomes****1****Description**

motor part of GCS

**Timepoint**

at biggining and two weeks later after treatment

**Method of measurement**

physical exam by physician

**2****Description**

glasgow outcome scale extended (GOSE)

**Timepoint**

at biggining and two weeks later after treatment

**Method of measurement**

physical exam by physician

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Zolpidem 10 mg PO BID for 2 weeks

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Emtiaz hospital

**Full name of responsible person**

Hossein Ali Khalili

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

hosseinali khalili

**Street address**

Central building of Shiraz University of Medical Sciences

**City**

Shiraz

**Province**

Fars

**Postal code**

71345-1978

**Phone**

+98 71 3235 7282

**Email**

vcrdep@sums.ac.ir

**Web page address**

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shiraz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

hosseinali khalili

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

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## Person responsible for scientific inquiries

#### Contact

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**Other areas of specialty/work**

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## Person responsible for updating data

#### Contact

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available