

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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

Street address

Emtiaz hospital, Chamran Blvd, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7194815711

Phone

+98 71 3625 4206

Email

khalili_h@sums.ac.ir

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

Street address

Emtiaz hospital, Chamran Blvd, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7194815711

Phone

+98 71 3625 4206

Email

khalili_h@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hosseinali Khalili

Position

Associat professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Rajae Hospital, Chamran Boulevard, Shiraz, Iran.

City

Shiraz

Province

Fars

Postal code

7194815711

Phone

+98 71 3624 8980

Fax

+98 71 3624 8980

Email

khalili_h@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

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Fax

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Email

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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