Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of zolpidem effect on level of conciousness 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)

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+98 71 3625 4206

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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 conciousness 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
glascow 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
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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 updating data

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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