Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of effect of thyroid hormone therapy on recovery of patients with moderate to severe traumatic brain injury at Emtiaz's hospital of Shiraz: a randomized clinical trial

Protocol summary

Study aim

Evaluation of effect of thyroid hormone therapy on recovery of patients with moderate to severe traumatic brain injury at Emtiaz's hospital of Shiraz

Design

Method will be used to generate the random allocation sequence is block randomization (A: intervention group & B: control group blocks: AABB, ABBA, BABA,BBAA, BAAB, ABAB); Mechanism will be used to implement the random allocation sequence will be sequentially numbered container, describing any steps taken to conceal the sequence until interventions were assigned.

Settings and conduct

All pure TBI Patients with inclusion criteria who are brought to Emtiaz hospital, since August 2021 to February 2022 and according to randomization & double blindness methods of the study divided to 2 groups: Intervention Group: who receive routine treatments and thyroid hormone therapy. Control Group: who just receive routine treatments and placebo. Stages: intervention: Routine treatment + Treatment with levothyroxine (1 tab 0.1mg QD for 3 weeks). control: Routine treatment + placebo (1 tab QD for 3 weeks). Check of TFT weekly & then after 3 month & after 6 month in both.

Participants/Inclusion and exclusion criteria

Patients who are brought to Emtiaz hospital, since August 2021 to February 2022. With Inclusion criteria to the study include: Pure moderate-to-severe TBI (GCS: motor score < 6) and Low normal TFT profile: T3 & T4 in first 25% of normal range + normal range of TSH. Exclusion criteria to the study include: Mild TBI, Patients with a pituitary abnormality on pituitary imaging, Patients who were unwilling to participate in the study or had not completed their investigations, History of Hyper or hypothyroidism, History of thyroid hormone therapy, History of thyroid surgery, and GCS=3 & GCS=4 with fixed pupils.

Intervention groups

Treatment with levothyroxine, orally (1 tab 0.1mg QD for 3 weeks).

Main outcome variables

ICU length of stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130310012776N6**
Registration date: **2021-09-30, 1400/07/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-30, 1400/07/08**
Update count: **0**

Registration date

2021-09-30, 1400/07/08

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

2021-09-23, 1400/07/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of effect of thyroid hormone therapy on recovery of patients with moderate to severe traumatic brain injury at Emtiaz's hospital of Shiraz: a randomized clinical trial

Public title
Evaluation of effect of thyroid hormone therapy on prognosis of patients with traumatic brain injury

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pure moderate-to-severe TBI (GCS: motor score < 6) Low normal TFT profile: T3 & T4 in first 25% of normal range normal range of TSH

Exclusion criteria:
Mild traumatic brain injury Patients with a pituitary abnormality on pituitary imaging Patients who were unwilling to participate in the study or had not completed their investigations History of Hyperthyroidism or hypothyroidism History of thyroid hormone therapy History of thyroid surgery Glasgow coma scale=3 & Glasgow coma scale=4 with fixed pupils

Age
From **16 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **266**

Randomization (investigator's opinion)
Randomized

Randomization description
Method will be used to generate the random allocation sequence is block randomization (A: intervention group & B: control group blocks: AABB, ABBA, BABA,BBAA, BAAB, ABAB); Mechanism will be used to implement the random allocation sequence will be sequentially numbered container, describing any steps taken to conceal the sequence until interventions were assigned.

Blinding (investigator's opinion)
Double blinded

Blinding description
participants and therapist physicians will be blinded to groups; (intervention: will be received thyroid hormone & control: will be received placebo). A physician who will evaluate patient's outcome, will be blinded to study groups, too.

Placebo
Used

Assignment
Parallel

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, Shahid Chamran Blvd

City
Shiraz

Province
Fars

Postal code
7194815711

Approval date
2021-06-14, 1400/03/24

Ethics committee reference number
IR.SUMS.MED.REC.1400.198

Health conditions studied

1

Description of health condition studied
Diffuse traumatic brain injury

ICD-10 code
S06.2

ICD-10 code description
Diffuse traumatic brain injury

Primary outcomes

1

Description
ICU length of stay

Timepoint
Since the time of trauma to discharge from the hospital

Method of measurement
Day

Secondary outcomes

1

Description
Glasgow outcome scale extended

Timepoint

Three & six month after traumatic brain injury

Method of measurement

Glasgow outcome scale extended

Intervention groups

1

Description

Intervention group: Patients with Pure moderate-to-severe TBI (GCS: motor score < 6) and low normal TFT profile: T3 & T4 in first 25% of normal range + normal range of TSH, will received Treatment with levothyroxine, orally (1 tab 0.1mg QD for 3 weeks).

Category

Treatment - Drugs

2

Description

Control group: Patients with Pure moderate-to-severe TBI (GCS: motor score < 6) and low normal TFT profile: T3 & T4 in first 25% of normal range + normal range of TSH, will received Treatment with placebo, orally (1 tab QD for 3 weeks).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emtiaz hospital

Full name of responsible person

Hosseinali Khalili

Street address

Emtiaz hospital, Shahid Chamran Blvd, Shiraz, Fars, Iran

City

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Phone

+98 71 3625 4206

Email

khalili_h@sums.sc.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research. Shiraz University of medical sciences

Full name of responsible person

Younes ghasemi

Street address

7th floor, Central building of Shiraz University of medical sciences

City

Shiraz

Province

Fars

Postal code

713451978

Phone

+98 71 3235 7282

Fax

+98 71 3212 2430

Email

vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor of research. 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

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
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Position
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
all data except personal patients data

When the data will become available and for how long
6 months after data publication

To whom data/document is available
all researcher

Under which criteria data/document could be used
no extra condition

From where data/document is obtainable
researcher should refer to Emtiaz hospital

What processes are involved for a request to access data/document
written request from Hosseinali Khalili

Comments