

# 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

Shiraz

##### Province

Fars

##### Postal code

7194815711

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

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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**