

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of thyroid function tests and effect of levothyroxin in prognosis of traumatic brain injury

Protocol summary

Study aim

Evaluation of thyroid function tests and effect of levothyroxin in prognosis of traumatic brain injury

Design

In this double blind clinical trial, 100 patients with brain trauma will be randomly assigned into two groups of levothyroxin and placebo

Settings and conduct

This study will be carried out at Tabriz Imam Hospital in a three-blind manner, only the head nurse will be aware of it, and the researcher and the patient and Analyzer will be unaware of it.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: patients 16 to 65 years of age, Having informed consent, patients with diffuse axonal injury, Exclusion criteria include: Receiving NSAIDs or corticosteroids, history of cardiac, respiratory, neuromuscular, hepatic or renal diseases, history of brain injuries, Having extra and intracranial space-occupying lesions

Intervention groups

Intervention group: Patients 3 day of after traumatic brain injury will receive twice daily levothyroxin 50 mg daily and this dose will continue for 6 weeks. Control group: placebo. receive placebo for 6 weeks (conditions similar)

Main outcome variables

Consciousness in patients, Glasgow coma scale, Glasgow Outcome Scale, mortality rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120527009878N13**

Registration date: **2020-02-08, 1398/11/19**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-08, 1398/11/19**

Update count: **0**

Registration date

2020-02-08, 1398/11/19

Registrant information

Name

Firooz Salehpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 0830

Email address

salehpourf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of thyroid function tests and effect of levothyroxin in prognosis of traumatic brain injury

Public title

Evaluation of thyroid function in prognosis of traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients 16 to 65 years of age Having informed consent to participate in the study Diffuse axonal injury in patients with head injuries

Exclusion criteria:

Receiving NSAIDS or corticosteroids history of cardiac, respiratory, neuromuscular, hepatic or renal diseases, history of brain injuries Having out and intracranial space-occupying lesions

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Random method: Block, Random unit: individual, Random Tool: Random Block 4. for this purpose, 25 blocks with 4 subjects in each block will be used. the combination of all patterns will be considered including AABB, ABAB, BABA, BBAA, BABA, BAAB. For selecting each blocks, dice drooped and the block number will be selected. this procedure continued to completed the allocation and reached to sample size.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This is a double-blinded study and Researcher and patients are kept unaware of intervention in each group and In order to allocation concealment, the type of intervention will be written on paper and placed in numbered, matte and packed envelopes. The envelopes will be opened in the order of participation of the participants and the type of group will be determined.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz Medical School

Street address

Azadi Ave , Golghast St , Imam Reza Hospital

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Approval date

2020-01-06, 1398/10/16

Ethics committee reference number

IR.TBZMED.REC.1398.1084

Health conditions studied

1

Description of health condition studied

Head Trauma

ICD-10 code

S06.2X

ICD-10 code description

Diffuse traumatic brain injury

Primary outcomes

1

Description

Consciousness in patients

Timepoint

daily until discharge

Method of measurement

Glasgow coma scale

2

Description

Glasgow Outcome Scale

Timepoint

pre-intervention and weekly until discharge

Method of measurement

Glasgow Outcome Scale questionnaire

3

Description

Disability Rating Scale (DRS) scoring

Timepoint

pre-intervention and weekly until discharge

Method of measurement

Disability Rating Scale questionnaire

Secondary outcomes

1

Description

mortality rate

Timepoint

In duration 6 weeks after traumatic brain injury

Method of measurement

Questionnaire on complications after traumatic brain injury

Intervention groups

1

Description

Intervention group: Patients 3 day of after traumatic brain injury will receive twice daily levothyroxin 50 mg and this dose will continue for 6 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurosurgery Ward of Emem Reza hospital

Full name of responsible person

Dr.Farhad Mirzaei

Street address

Azadi St, Golghast Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3334 7054

Email

golzar.farhad@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ali Meshkini

Street address

Azadi St., Golghast Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3336 3176

Email

Meshkinia@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Firoz Salehpoor

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Neurosurgery ward, Emam Reza Hospital, Gholghasht Street, Azadi Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 1334 0830

Email

salehpourf@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Farhad Mirzaei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Neurosurgery ward, Emam Reza Hospital, Gholghasht Street, Azadi Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 1334 0830

Email

golzar.farhad@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Amin Parizad

Position

Resident of Neurosurgery

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

Street address

Neurosurgery ward, Emam Reza Hospital, Gholghasht
Street, Azadi Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3334 7054

Email

parizadamin@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

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

Title and more details about the data/document

A portion of the data that represents the final outcome

**When the data will become available and for how
long**

Access will be 6 months after the results are printed.

To whom data/document is available

Neuropsychiatric specialists in coordination with the
presenter

Under which criteria data/document could be used

The use of data to improve patients' treatment processes
is safe

From where data/document is obtainable

Person responsible for updating study information

**What processes are involved for a request to access
data/document**

Requesting data and study documents will be done by
correspondence with the person responsible for updating
the study information

Comments