

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Difficult weaning of mechanical ventilation due to hypothyroidism

Protocol summary

Study aim

The aim of current study is to investigate the role of hypothyroidism in difficult weaning from mechanical ventilation.

Design

Clinical trial study, with parallel groups, double blinded, randomized

Settings and conduct

80 patients under mechanical ventilation for more than a week were enrolled the study and were divided in two equal group, randomly. The first group received routine treatment and the second group received the first 0.1 milligram levothyroxine daily in addition to the routine treatments. The outcome of treatment and the possibility of weaning were evaluated between the two groups. The findings were compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients without previously known thyroid disease Mechanical ventilation more than one week Exclusion criteria: Brain and lung diseases History of interfering drugs with thyroid consumption such as Lithium Patient dissatisfaction History of heart diseases Arrhythmia without cause Patients with history of Hypothyroidism

Intervention groups

Intervention group: Levothyroxine prescription Control group: Non-prescribed levothyroxine

Main outcome variables

Weaning time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120605009948N7**

Registration date: **2019-09-10, 1398/06/19**

Registration timing: **retrospective**

Last update: **2020-11-12, 1399/08/22**

Update count: **1**

Registration date

2019-09-10, 1398/06/19

Registrant information

Name

Majid Montazer

Name of organization / entity

Tabriz University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 8435

Email address

montazerma@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

2018-03-06, 1396/12/15

Actual recruitment end date

2019-01-27, 1397/11/07

Trial completion date

2019-03-01, 1397/12/10

Scientific title

Difficult weaning of mechanical ventilation due to hypothyroidism

Public title

Hypothyroidism in mechanical ventilation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients without previously known thyroid disease
Mechanical ventilation more than one week

Exclusion criteria:
Brain and lung diseases History of interfering drugs with thyroid consumption such as Lithium Patient dissatisfaction History of heart diseases Arrhythmia without cause Patients with history of Hypothyroidism

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **80**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals with inclusion criteria were recruited by a non-random sample method. Then, random allocation was done to form study groups. In this study, a block randomization method (including quadruple blocks) was used. One of non-blinded colleagues of this study, named the catheter implantation method with the letters A and B. Then, the researcher distributed A and B envelopes among patients in a randomized block method for participating in the study. Then, selecting the blocks was continued until achieving the sample size. The method of making random sequence was done using a simple randomization. To make a random sequence for the possible blocks, (6 blocks) we gave numbers to them from 1 to 6. Regarding the sample size, the required quadruple number of blocks was used. The number of blocks was chosen from the random numbers table and based on these numbers the sequence of blocks in each group was identified.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, blinding was carried out as follows: The data collector : because of the lack of information about the prescription or not of levothyroxine was blinded. Patients were blinded: because they were not supposed to be aware of the levothyroxine prescription
Blinding/Blindfolding Method: Based on the sequence of random numbers, the groups A or B were placed inside sealed envelopes. A researcher who was not aware of the contents and sequence of the envelopes respectively opened the envelopes, and depending on whether they were A or B, levothyroxine was prescribed for them or not. Only one member of team knew A or B was according to which catheter implantation method.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences., Golgasht St., Azadi St

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2017-02-16, 1395/11/28

Ethics committee reference number

IR.TBZMED.REC.1395.1226

Health conditions studied

1

Description of health condition studied

Hypothyroidism

ICD-10 code

E03

ICD-10 code description

Other hypothyroidism

Primary outcomes

1

Description

Weaning time

Timepoint

Daily

Method of measurement

Using the questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Levothyroxine prescription at a daily dose of 0.1 mg through the nasogastric tube until extubation (Sodium levothyroxine tablet, Iran hormone product)

Category

Treatment - Drugs

2

Description

Control group: Non-prescribed levothyroxine

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Majid Montazer Bavi

Street address

Imam Reza Hospital, Golgasht St., Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5166615556

Phone

+98 41 3334 7056

Email

info@imamreza.tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Vice-Chancellor of research, Tabriz University of Medical Sciences

Street address

Golgasht Ave.,

City

Tabriz

Province

East Azarbaijan

Postal code

5166615556

Phone

+98 41 3333 5333

Email

skshakouri@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

Mahid Montazer Bavi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Daneshghah Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166615556

Phone

+98 41 3335 7852

Email

montazerma@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Majid Montazer Bavi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Daneshghah Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166615556

Phone

+98 41 3335 7852

Email

montazerma@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Majid Montazer Bavi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Daneshgah Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166615556

Phone

+98 41 3335 7852

Email

montazerma@tbzmed.ac.ir

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

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

Not applicable

Title and more details about the data/document

We have not yet set a conclusion

When the data will become available and for how long

We have not yet set a conclusion

To whom data/document is available

We have not yet set a conclusion

Under which criteria data/document could be used

We have not yet set a conclusion

From where data/document is obtainable

We have not yet set a conclusion

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

We have not yet set a conclusion

Comments