Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 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

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Iran (Islamic Republic of)

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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 Bavil
Street address
Imam Reza Hospital, Golgasht St., Azadi Ave
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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.,
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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 Bavil
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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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
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