

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

the effect of oral liothyronin in patients outcome with congenital Cardiac surgery

Protocol summary

Study aim

replacement of thyroid hormone improve cardiopulmonary function and reduce in the patients that hospitalised in icu after cardiac surgery

Design

randomized trial blinded

Settings and conduct

modares hospital

Participants/Inclusion and exclusion criteria

80 patients(upper 6 mounths and lower 5 years) under cardiac surgery with cardiopulmonary bypass

Intervention groups

group1 20 patients receive with placbo group2 20 patients receive liothyronine(2 microgram perKg) one day befor surgery group3 20 patients receive liothyronine one day before surgery and day of surgery befor cardiopumounary bypass group4 20 patients receive liothyronine one day befor surgery and day of surgery before cardiopumounary bypass and after surgery in icu(2 microgram perKg)and ckeck the T3 T4 TSH FT4 TOTAL T4 IN 3 times

Main outcome variables

long of hospitalized in icu. long of intubation .inotrop dose .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180502039507N1**

Registration date: **2019-04-27, 1398/02/07**

Registration timing: **retrospective**

Last update: **2019-04-27, 1398/02/07**

Update count: **0**

Registration date

2019-04-27, 1398/02/07

Registrant information

Name

Alireza Omid farzin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4465 4351

Email address

alirezaomidi@sbum.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-16, 1397/03/26

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of oral liothyronin in patients outcome with congenital Cardiac surgery

Public title

the effect of oral liothyronin in patients outcome with congenital Cardiac surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

in this study that do randomize 80 pateint (upper6 mounths lower 5years)with under cardiopulmonary bypas in cardiac surgery

Exclusion criteria:

impaired thyroid function test befor surgery

Age

From **6 months** old to **60 months** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

patients and physicians and analysts are blind but immune committee aware from interventions

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of medical science

Street address

Modaress hospital saadat abad ave.Tehran .Iran

City

Tehran

Province

Tehran

Postal code

1393845861

Approval date

2018-05-15, 1397/02/25

Ethics committee reference number

IR.SBMU.MSP.REC.1397.609

Health conditions studied

1

Description of health condition studied

Sick euthyroid syndrome

ICD-10 code

E07.81

ICD-10 code description

Sick-euthyroid syndrome

Primary outcomes

1

Description

Effect of levothyronine in cardiac function after cardiac surgery(long of intubation.long of icu admission.inotrope dosage)

Timepoint

Thyroid function test before surgery and 24 hours after surgery

Method of measurement

Icu admission and long of intubation based on day. and inotrope dose microgram per kilogram

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1 placebo

Category

Early detection

2

Description

Intervention group: 20 patients before surgery give 2micro per kilogram levothyronine

Category

Early detection

3

Description

Intervention group:20 patients before surgery give 2micro per kilogram levothyronine and repeat in intubation before cardiopulmonary bypass

Category

Early detection

4

Description

Intervention group: 20 patients before surgery give 2micro per kilogram levothyronine and repeat in intubation before cardiopulmonary bypass and after surgery repeat the levothyronine

Category

Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center

Modares hospital

Full name of responsible person

Alireza Omid

Street address

Modares hospital Saadat abad ave.Tehran .Iran

City

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Phone

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Email

ttdzh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Alireza Omid

Street address

Modares hospital Saadat abad ave.Tehran.Iran

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Alireza Omid Farzin

Position

Cardiac surgeon

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Alireza Omid Farzin

Position

Cardiac surgeon

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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

proposal

When the data will become available and for how long

1year

To whom data/document is available

students

Under which criteria data/document could be used

1year

From where data/document is obtainable

library of modares hospital

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

cardiac surgery

Comments