Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 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 cardiopumonary bypass group4 20 patients receive liothyronine one day befor surgery and day of surgery before cardiopumonary 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 Omidi 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
pateints and physicions and analysors are blind but immune commite aware from interventions
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Shahid Beheshty 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 addmition.inotrope dosage)
Timepoint
Thyroid function test befor surgery and 24 hours after surgery
Method of measurement
Icu addmision and long of intubation based on day. and inotrope dose micrgram per kilogram

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 1 placbo
Category
Early detection

2

Description
Intervention group: 20 patients befor surgery give 2micro per kilogram levothyronine
Category
Early detection

3

Description
Intervention group:20 patients befor surgery give 2micro per kilogram levothyronine and repeat in intubation befor cardiopulmonary bypase
Category
Early detection

4

Description
Intervention group: 20 patients befor surgery give 2micro per kilogram levothyronine and repeat in intubation befor cardiopulmonary bypase 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 Omidi

Street address
Modaress hospital Saadat abad ave.Tehran .Iran

City
Tehran

Province
Tehran

Postal code
1393845861

Phone
+98 21 4465 4351

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 Omidi

Street address
Modaress hospital Saadat abad ave.Tehran.Iran

City
Tehran

Province
Tehran

Postal code
1393845861

Phone
+98 21 4465 4351

Email
ttdzh@yahoo.com

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 Omidi Farzin

Position
Cardiac surgeon

Latest degree
Subspecialist

Other areas of specialty/work
Cardiology

Street address
Modaress hospital Saadat abad ave.Tehran .Iran

City
Tehran

Province
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Phone
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Email
ttdzh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Alireza Omidi Farzin

Position
Cardiac surgeon

Latest degree
Subspecialist

Other areas of specialty/work
General Surgery

Street address
Modaress hospital Saadat abad ave.Tehran .Iran

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Phone
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Email
ttdzh@yahoo.com

Person responsible for updating data

Contact

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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