

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Studying the relationship between neonatal hypothyroidism and using iodine and non iodine containing disinfectants before cesarian section in icteric neonates that refer to clinic of neonates in Valiasr hospital

Protocol summary

Summary

The purpose of this study is to understand whether neonatal hypothyroidism have any relationship with using iodine containing disinfectants during preparation for cesarean section or not. Inclusion criteria: all the mothers which are delivered during 12 month (case gathering period) in emergency department of Valiasr Hospital. Exclusion criteria: mothers that were applied iodine containing disinfectant and thyroid medications before delivery or neonates that were applied these disinfectants or medications during the study period; mothers or neonates which have a systemic disease; mothers with high risk pregnancies. This is a nonrandomised clinical trial which will perform in Valiasr hospital and for cesarean section preparation for 6 consecutive months we will use povidone iodine and for another 6 consecutive months we will use chlorhexidine. We will assay TSH & T4 (ELISA) in cord blood and in neonates which will return for evaluating jaundice in 3-5 th days of life. Sample size in each group was estimate 300 cases. If these neonates have hypothyroidism we will assay TSH & T4 in 2 nd and 4 th week and also we will evaluate their mother's thyroid function.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204289568N1**
Registration date: **2012-07-07, 1391/04/17**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-07-07, 1391/04/17

Registrant information

Name

Golnaz Rezaeizadeh

Name of organization / entity

Maternal Fetal Neonatal Research Center, Tehran
University of Medical Sciences, Tehran, Iran

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2357

Email address

mfnhrc@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the relationship between neonatal hypothyroidism and using iodine and non iodine containing disinfectants before cesarian section in icteric neonates that refer to clinic of neonates in Valiasr hospital

Public title

Effect of using iodine containing disinfectant in delivery on neonate's thyroid

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:all the mothers which are delivered during 12 month (case gathering period) in emergency department of Valiasr Hospital Exclusion criteria:mothers that were applied iodine containing disinfectant and thyroid medications before delivery or neonates that were applied these disinfectants or medications during the study period; mothers or neonates which have a systemic disease; mothers with high risk pregnancies.

Age

To **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **600**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Ethics committee of Tehran University of Medical Sciences,6 th floor of Tehran University of Medical Sciences,ghods St., Keshavarz blv,Tehran, Iran

City

Tehran

Postal code

Approval date

2012-04-15, 1391/01/27

Ethics committee reference number

49274

Health conditions studied

1

Description of health condition studied

neonatal hypothyroidism

ICD-10 code

E03.2

ICD-10 code description

Hypothyroidism due to medicaments and other exogenous substances Use additional external cause code (Chapter XX), if desired, to identify cause.

Primary outcomes

1

Description

neonatal hypothyroidism

Timepoint

one time from cord at birth and another time in clinic

Method of measurement

evaluation in laboratory.Measure:yes/no

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:using clorhexidine 4% (a disinfectant without iodine & FDA approved) for 6 consecutive months for preparation of mothers which are candidated for cesarean section

Category

Prevention

2

Description

Control group: using Povidone Iodine(a disinfectant with iodine) for 6 consecutive months for preparation of mothers which are candidated for cesarean section

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

golnaz rezaeizadeh/MD

Street address

Vaiasr hospital,Imam Khomeini Hospital complex, Keshavarz blv,14914, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Maternal Fetal Neonatal Research Center,Tehran
University of Medical Sciences

Full name of responsible person

Mamak Shariat

Street address

Vaiasr hospital,Imam Khomeini Hospital complexex,
Keshavarz blv, Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Maternal Fetal Neonatal Research Center,Tehran
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Maternal Fetal Neonatal Research Center,Tehran
University of Medical Sciences, Tehran, Iran

Full name of responsible person

golnaz rezaeizadeh

Position

researcher/MD

Other areas of specialty/work**Street address**

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Person responsible for scientific

inquiries

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Position

professor/neonatologist

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Person responsible for updating data

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Position

researcher/MD

Other areas of specialty/work**Street address**

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty