

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of the effects of two dose of iodine supplements on lactating mothers' and breast-fed infants' iodine nutrition status and comparing to formula-fed infants: From birth to one year

#### Protocol summary

##### Summary

Objective: Evaluation of the effects of two dose of iodine supplements on lactating mothers' and breast-fed infants' iodine nutrition status and comparing to formula-fed infants Design: Multicentre clinical trial Methods: A- subjects- Major inclusion criteria: Lactating mothers, breast-fed and formula-fed infants- Major exclusion criteria: Thyroid diseases in mothers and hypothyroidism in neonates -Sample size: 208 B-intervention: Supplements containing 150 and 300 micrograms iodine C- Intervention time: Assessment of breast milk iodine and urinary iodine concentration in mothers and infants in 3-5 days, 1, 2, 4, 6, 9, 12 months D- Main outcome: breast milk iodine and urinary iodine concentrations

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201303164794N8**  
Registration date: **2013-05-20, 1392/02/30**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-05-20, 1392/02/30

##### Registrant information

##### Name

Fereidoun Azizi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2240 9309

##### Email address

azizi@endocrine.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Institute for Endocrine Science, Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2013-06-22, 1392/04/01

##### Expected recruitment end date

2014-06-22, 1393/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effects of two dose of iodine supplements on lactating mothers' and breast-fed infants' iodine nutrition status and comparing to formula-fed infants: From birth to one year

##### Public title

Iodine supplementation and iodine nutrition in lactating mothers and their breast-fed infants

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: lactating mother; full-term infants (37-42 weeks) with normal birth weight (2500-4200 g); neonate with age 3-5 days Exclusion criteria: Thyroid diseases in lactating mothers and their infants; Taking thyroid medications; using self-order iodine containing supplements; using iodinated antiseptics; neonate hypothyroidism

##### Age

From **15 years** old to **45 years** old

## Gender

Female

## Phase

2-3

## Groups that have been masked

No information

## Sample size

Target sample size: **208**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee, Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical S

##### Street address

No. 24, Shahid Aerabi St., Yemen St., Chamran Exp.

##### City

Tehran

##### Postal code

##### Approval date

2013-02-26, 1391/12/08

##### Ethics committee reference number

23ECRIES

## Health conditions studied

### 1

#### Description of health condition studied

iodine deficiency

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Urinary iodine concentration in breast milk-fed infants

#### Timepoint

3-5 days, 1, 2, 4, 6, 9, and 12 months after birth

#### Method of measurement

Acid- Digestion

## Secondary outcomes

### 1

#### Description

Urinary iodine concentration in lactating mothers

#### Timepoint

3-5 days, 1, 2, 4, 6, 9, and 12 months after delivery

#### Method of measurement

Acid Digestion

### 2

#### Description

Breast milk iodine concentration

#### Timepoint

3-5 days, 1, 2, 4, 6, 9, and 12 months after delivery

#### Method of measurement

Acid Digestion

### 3

#### Description

Urinary iodine concentration in formula-fed infants

#### Timepoint

3-5 days, 1, 2, 4, 6, 9, and 12 months after birth

#### Method of measurement

Acid Digestion

## Intervention groups

### 1

#### Description

Intervention Groups: Supplements containing 150 and 300 micrograms iodine

#### Category

Other

### 2

#### Description

Control Group: Placebo

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Health Care Centers in the south of Tehran

##### Full name of responsible person

Expert in mother's and child's health

##### Street address

##### City

Tehran

## Sponsors / Funding sources

## 1

### **Sponsor**

**Name of organization / entity**

Vice Chancellor for Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical

**Full name of responsible person**

Prof. Fereidoun Azizi

**Street address**

No. 24, Shahid Aerabi St., Yemen St., Chamran Exp.

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical

**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**

Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Prof. Fereidoun Azizi

**Position**

Professor, Professor of internal medicine and endocrinology/ Director of Research Institute for Endo

**Other areas of specialty/work**

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**Web page address**

### **Person responsible for scientific inquiries**

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**Full name of responsible person**

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### **Person responsible for updating data**

**Contact**

**Name of organization / entity**

Nutrition and Endocrine Research Center, Research Institute for Endocrine Sciences, Shahid beheshti

**Full name of responsible person**

Pantea Nazeri

**Position**

PhD by Research student, MSc in Nutrition Sciences/ Researcher

**Other areas of specialty/work**

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### **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*