

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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

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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

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

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

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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Person responsible for scientific inquiries

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Position

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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