Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 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 lacatating 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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Person responsible for scientific inquiries

Contact

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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