

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jun 2026

Evaluation of the effects of iodine fortified-milk on lactating mothers' and their infants' iodine nutrition status

Protocol summary

Summary

Objective: Evaluation of the effects of iodine fortified-milk on lactating mothers' and their infants' iodine nutrition status. Design: Multicenter clinical trial. Setting and conduct: A-Participants including major eligibility criteria- Major inclusion criteria: Lactating mothers and their infants Major exclusion criteria: Thyroid diseases in mothers and their infants, neonate hypothyroidism- Sample size:52 B- Intervention: Iodine-enriched milk C- Intervention time: 3-5, 7, 10,14 days and 1, 2 months after delivery D-Main outcome: Breast milk and urinary iodine concentrations

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305074794N9**
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

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

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of iodine fortified-milk on lactating mothers' and their infants' iodine nutrition status

Public title

Iodine fortified-milk and iodine nutrition in lactating mothers and their infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:Lactating mothers; full-term infants(37-42 weeks) with normal birth weight (2500-4200 g); neonates with age 3-5 days. Exclusion criteria: Having thyroid diseases; taking anti- thyroid medications; using iodine containing supplements; 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: **52**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
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

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, 7, 10, 14 days, 1, and 2 months after birth

Method of measurement

Acid- Digestion

Secondary outcomes

1

Description

Urinary iodine concentration in lactating mothers

Timepoint

3-5, 7, 10, and 14 days, 1 and 2 months after delivery

Method of measurement

Acid Digestion

2

Description

Breast milk iodine concentration

Timepoint

3-5, 7, 10, and 14 days, 1 and 2 months after delivery

Method of measurement

Acid Digestion

Intervention groups

1

Description

Intervention Group: Iodine fortified-milk

Category

Prevention

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

Tehran

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Web page address**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**Street address**

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Web page address**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

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Full name of responsible person

Prof. Fereidoun Azizi

Position

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

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City**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