

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Designing and evaluation of an educational package to provide of adequate iodine status during pregnancy

Protocol summary

Summary

The purpose of the present study is to design and evaluate the effectiveness of an educational program regarding iodine intake and iodized salt on knowledge, attitude and practice levels and the iodine nutrition status of pregnant women. This survey is a semi experimental study (intervention-control) and single blind. 100 pregnant women, residents of southern Tehran, being the first trimester of pregnancy, referred to five health care centers will randomly select. Inclusion criteria will be pregnant women in the first trimester, without thyroid diseases and high blood pressure and willing to cooperate. Exclusion criteria will be having any thyroid diseases and hypertension during pregnancy and unwilling to cooperate. demographic characteristic and knowledge, attitude and practice status regarding the importance of iodine and iodized salt consumption will examine via two questionnaire and their iodine status will determine using urinary iodine concentration (UIC) and iodine content of salt in two steps at a distance of four months. intervention group will be received the education based on designed educational program in the second and third trimester.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602035440N5**

Registration date: **2016-02-28, 1394/12/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-28, 1394/12/09

Registrant information

Name

Parisa Amiri

Name of organization / entity

Obesity research center

Country

Iran (Islamic Republic of)

Phone

+98 21 2240 9309

Email address

amiri@endocrine.ac.ir

Recruitment status

Recruitment complete

Funding source

Research institute for endocrine sciences Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2016-08-21, 1395/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing and evaluation of an educational package to provide of adequate iodine status during pregnancy

Public title

consumption of iodine during pregnancy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Being the first trimester of pregnancy, without thyroid diseases and high blood pressure, willing to cooperate. Exclusion criteria: having any thyroid diseases and hypertension during pregnancy and unwilling to cooperate.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Participants will randomly allocated into the intervention or control groups (n = 50 each), using a random number table.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

7th Floor , 2nd SBUMS Bldg. , Aarabi St., Yaman St., Next to Ayatollah Taleghani Hospital, Tehran, Iran.

City

Tehran

Postal code

198396-3113

Approval date

2014-06-10, 1393/03/20

Ethics committee reference number

715

Health conditions studied**1****Description of health condition studied**

Iodine status

ICD-10 code

-

ICD-10 code description**Primary outcomes****1****Description**

knowledge

Timepoint

before intervention and 4 months later

Method of measurement

questionnaire

2**Description**

attitude

Timepoint

before intervention and 4 months later

Method of measurement

questionnaire

3**Description**

practice

Timepoint

before intervention and 4 months later

Method of measurement

questionnaire

4**Description**

urinary iodine concentration

Timepoint

before intervention and 4 months later

Method of measurement

acid digestion

5**Description**

content of salt iodine

Timepoint

before intervention and 4 months later

Method of measurement

iodometric titration

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: the educational program will last four months, and included two face to face educational sessions using a researcher-designed educational pamphlet in the second and the third trimesters; in addition, 2 follows-up by telephone calls will make between educational sessions. urinary iodine concentration (UIC) and salt iodine content will gather at

baseline and 4 months after the intervention.

Category

Behavior

2

Description

control group: will receive the education usually via health workers provided in health care centers. urinary iodine concentration (UIC) and salt iodine content will gather at baseline and 4 months after the intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohammad Bagher health care center

Full name of responsible person

Najmeh Hamzavi Zarghani

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Emam Sadegh health care center

Full name of responsible person

Najmeh Hamzavi Zarghani

Street address

City

Tehran

3

Recruitment center

Name of recruitment center

Dadvash health care center

Full name of responsible person

Najmeh Hamzavi Zarghani

Street address

City

Tehran

4

Recruitment center

Name of recruitment center

Ayat health care center

Full name of responsible person

Najmeh Hamzavi Zarghani

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research institute for endocrine sciences

Full name of responsible person

Professor Fereidoun Azizi

Street address

Aarabi St., Yaman st., Shahid Chamran Highway, 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

Research institute for endocrine sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Research institute for endocrine sciences, Shahid Beheshti University

Full name of responsible person

Fereidoun Azizi Professor

Street address

Aarabi st., Yaman St., Shahid Chamran Highway, Tehran, Iran,

City

Tehran

Grant name

-

Grant code / Reference number

-

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Yes

Title of funding source

Research institute for endocrine sciences, Shahid Beheshti University

Proportion provided by this source

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 Center for Social Determinants of Endocrine
Health & Obesity Research Center, Research Inst

Full name of responsible person

Parisa Amiri

Position

Health education and promotion PhD

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

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Fax**Email****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