

# 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**

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

**City**

Tehran

**Postal code****Phone**

+98 21 2243 2500

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amiri@endocrine.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Tehran

**Postal code****Phone**

+98 21 2243 2500

**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*