

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Assessment of changes in thyroid hormones and iodine in urine with mild and short-term social stress in male and female students in Urmia

#### Protocol summary

##### Study aim

This study aimed to investigate changes of T3 and iodine concentrations in urine of elementary students following a mild and short-term social stress in Urmia city.

##### Design

In this study, 160 students from both sexes (80 girls and 80 boys) will randomly be chosen. A mild and short-term social stress will be applied to half of the students. Before and after stress, urine sample will be collected and T3 and Iodine concentrations will be determined. Also, heart rate and blood pressure will be measured before and after stress.

##### Settings and conduct

This study will be done in elementary schools of Danesh and Setayesh in Urmia city with presence of students' family.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: students in grade 4 to 6 without any recognized illness and drug usage that they and their families are volunteers to participate in the study.  
Exclusion criteria: Students who have had a major family problem in the last two months, such as parental divorce, the death of one of the parents, and the death of the first grade relative. Students who have had severe illness in the past month and endorsed by our endocrinologist or psychiatrist colleagues. Students who do not have normal physical growth, such as dwarfs and giants

##### Intervention groups

control group will be studied without exposure to stress. group stress will be exposed to a mild and short term stress. The both groups will be studied before and after, also.

##### Main outcome variables

heart rate; blood pressure; stress score; T3 and iodine concentration in urine

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171015036779N2**  
Registration date: **2018-02-11, 1396/11/22**  
Registration timing: **prospective**

Last update: **2018-02-11, 1396/11/22**

Update count: **0**

##### Registration date

2018-02-11, 1396/11/22

##### Registrant information

##### Name

Ehsan Saboory

##### Name of organization / entity

Urmia U of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 32780803

##### Email address

saboory@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Urmia university of medical sciences

##### Expected recruitment start date

2018-04-13, 1397/01/24

##### Expected recruitment end date

2018-05-25, 1397/03/04

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessment of changes in thyroid hormones and iodine

in urine with mild and short-term social stress in male and female students in Urmia

### Public title

Effect of stress on thyroid hormones

### Purpose

Basic science

### Inclusion/Exclusion criteria

#### Inclusion criteria:

students at grade 4 to 6 in elementary schools without any recognized illness and drug application

#### Exclusion criteria:

students who had a certain family problem in the last two months such as separation of parents, the death of mother or father, the death of relatives of first degree student who had a severe illness in the last month diagnosed by endocrinologist and psychiatric colleagues students who have not normal growth such as dwarfs and giants

### Age

From **9 years** old to **12 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant

### Sample size

Target sample size: **160**

### Randomization (investigator's opinion)

Randomized

### Randomization description

To allocate 80 students to the intervention groups, we will use a random block method. We will use blocks of size 4. This method of randomization will yield balance number of students in two groups. The blocks and their random order are defined before the random selection of students, and will be concealed among on the research team members. At each elementary school, list of all students of fourth, fifth and sixth grade are obtained from school officials. Then, we will give an identification number from 1 to N to each student. Then, using a random number table, 100 students will be selected from each school (i.e., students will be randomly selected from the school). (We consider a 20% chance of not agreeing to participate in the study by the students' parents). The selection order of the students will be recorded. After obtaining the informed consent from the parents of the students, we will match the selection order of the students with the predefined order of the blocked randomization to identify the group that the students will enter to it

### Blinding (investigator's opinion)

Single blinded

### Blinding description

students will be divided into two groups as group one and group two. the students and their teachers are not informed of the group differences.

### Placebo

Not used

### Assignment

Parallel

### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Urmia university of medical sciences

##### Street address

Blv resalat, End of Jihad street, next to emergency center Urmia

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5556115111

#### Approval date

2017-09-20, 1396/06/29

#### Ethics committee reference number

IR.UMSU.REC.1395.435

### Health conditions studied

#### 1

#### Description of health condition studied

endocrine and metabolic

#### ICD-10 code

#### ICD-10 code description

### Primary outcomes

#### 1

#### Description

Thyroid hormones

#### Timepoint

before stress and two hours after it

#### Method of measurement

ready to use Eliza kit

#### 2

#### Description

Urinary iodine concentration

#### Timepoint

before and after stress

#### Method of measurement

ready to use ELIZA kit

### Secondary outcomes

## 1

### Description

heart rate

### Timepoint

before and after stress

### Method of measurement

counting the heart beat in one minute

## 2

### Description

blood pressure

### Timepoint

before and after stress

### Method of measurement

sphygmomanometer

## Intervention groups

## 1

### Description

stress group: In the morning at 9 heart rate and blood pressure of the students will be recorded and urine sample will be obtained. Reading and presenting one page text from student's Farsi book in each grade in front of researchers, teachers and staff of the school will be performed by the students. This is conceptualized as mild social stress. two h later recording of heart rate and blood pressure and obtaining urine sample will be repeated.

### Category

Behavior

## 2

### Description

Control group: the students will be studied without any intervention. At 9 am heart rate and blood pressure of the students will be recorded and urine sample will be obtained. the procedure will be repeated 120 minutes later.

### Category

Behavior

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Elementary school Setayesh

#### Full name of responsible person

Narges Norooz Tamar

#### Street address

Next to Baba taher street, Sadi street

#### City

Urmia

#### Province

West Azarbaijan

#### Postal code

5719187497

### Phone

+98 44 3367 4330

### Email

ehsan.db@gmail.com

## 2

### Recruitment center

#### Name of recruitment center

elementary school Danesh

#### Full name of responsible person

Roghayeh Moradi

#### Street address

Next to Baba taher street, Sadi street

#### City

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#### Province

West Azarbaijan

#### Postal code

5719166943

#### Phone

+98 44 3368 6130

#### Email

ehsaan48@hotmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Oroumia University of Medical Sciences

#### Full name of responsible person

Dr Iraj Mohebbi

#### Street address

End of Jihad street, Resalat BLdv

#### City

Urmia

#### Province

West Azarbaijan

#### Postal code

5714783734

#### Phone

+98 44 3222 2010

#### Email

malizade1@gmail.com

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Oroumia University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

Public

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

empty

### Country of origin

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Ehsan Saboory

**Position**

Prof in physiology, academic member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

neuroendocrinology

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Ehsan Saboory

**Position**

professor in physiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiology

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**Postal code**

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**Email**

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

Oroumia University of Medical Sciences

**Full name of responsible person**

Ehsan saboory

**Position**

PhD in physiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiology

**Street address**

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**City**

Urmia

**Province**

West Azarbaijan

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Personal information is confidential and should not be published

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable