

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Prevention of non-communicable disease in a population in nutrition transition: Tehran Lipid and Glucose Study (Phase II)

Protocol summary

Summary

Background and objectives: The Tehran Lipid and Glucose Study (TLGS) is a long term integrated community-based program for prevention of non-communicable disorders (NCD) by development of a healthy lifestyle and reduction of NCD risk factors. The study begun in 1998, is ongoing, to be continued for at least 20 years. A primary survey was done to collect baseline data in 15005 individuals, over 3 years of age, selected from cohorts of three medical health centers. A questionnaire for past medical history and data was completed during interviews; blood pressure, pulse rate, and anthropometrical measurements and a limited physical examination were performed and lipid profiles, fasting blood sugar and 2-hours-postload-glucose challenge were measured. A DNA bank was also collected. For those subjects aged over 30 years, Rose questionnaire was completed and an electrocardiogram was taken. Data collected were directly stored in computers as database software- computer assisted system. The aim of this study is to evaluate the feasibility and effectiveness of lifestyle modification in preventing or postponing the development of NCD risk factors and outcomes in the TLGS population. Design & Methods: In phase II of the TLGS and as a controlled field trial, lifestyle interventions were implemented in 5630 people (one of the 3 medical centers which it was far from two others) and 9375 individuals served as controls. Primary, secondary and tertiary interventions were designed based on specific target groups including schoolchildren, housewives, and high-risk persons. Officials of various sectors such as health, education, municipality, police, media, traders and community leaders were actively engaged as decision makers and collaborators. Interventional strategies were based on lifestyle modifications in diet, smoking and physical activity through face-to-face education, leaflets & brochures, school program alterations, training volunteers as health team and treating patients with

NCD risk factors. Collection of demographic, clinical and laboratory data (as primary outcomes) will be repeated every 3 years to assess the effects of different interventions in the intervention group as compared to control group. Secondary outcomes (including cardiovascular events, CVA, cancers, and any other significant medical conditions) are measured annually.

General information

Acronym

TLGS II

IRCT registration information

IRCT registration number: **IRCT138705301058N1**

Registration date: **2008-10-29, 1387/08/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2008-10-29, 1387/08/08

Registrant information

Name

Arash Ghanbarian

Name of organization / entity

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

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

This study has been approved and funded by the National Research Council of the Islamic Republic of Iran (No. 121)

Expected recruitment start date

1998-12-22, 1377/10/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prevention of non-communicable disease in a population in nutrition transition: Tehran Lipid and Glucose Study (Phase II)

Public title

Lifestyle modification for Prevention of non-communicable disorders: Intervention phase of the Tehran Lipid and Glucose Study (phase II)

Purpose

Supportive

Inclusion/Exclusion criteria

Individuals aged 3 years and over who were residence of the District 13 of Tehran and were under the coverage of three medical health centers of Salavati, Mohammadian, and Lailatolghadr, were selected using multistage cluster random sampling method. All members of each family not mentally disabled, including those having or not having risk factors, were interviewed.

Age

From 3 years old to 99 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 15005

Randomization (investigator's opinion)

Not randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

This study has been approved by the National Research Council of the Islamic Republic of Iran (No. 1

Street address

The Human Research Review Committee of the Endocrine Research Center, Shahid Beheshti University

City

Tehran

Postal code**Approval date**

1999-11-21, 1378/08/30

Ethics committee reference number

121

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

Lifestyle modification interventions in preventing or postponing the development of NCD risk factors and outcomes with special focus on angina pectoris, myocardial infarction, cerebrovascular events, diabetes mellitus, hypertension and dyslipidemia.

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

Major NCD risk factors including glucose disorders, dyslipidemia, obesity, smoking, HTN, level of physical activity, nutritional status

Timepoint

every 3 years

Method of measurement

The participants are interviewed by trained physicians to obtain past medical history and to complete a 110-item questionnaires regarding familial history of NCD, smoking habits, reproductive history and assessment of physical activity; brief physical examination is performed including anthropometric measurements. Rose angina questionnaire is completed and ECG is taken from individuals over 30 years of age. Trained dietitians collect dietary data in one tenth of the participated family.

Secondary outcomes**1****Description**

any medical event with special focus on cardiovascular events

Timepoint

one year

Method of measurement

Every participant of the TLGS is followed up for any medical event during prior year by telephone call. He/she

is asked for any medical conditions by a trained nurse and if a related event had occurred a trained physician collects complementary data during a home visit. If necessary, she pays a visit to respected hospital and collects data from medical files. In the case of mortality, data are collected from hospital or death certificate by local physician. The collected data were then evaluated by an outcome committee to assign a specific outcome for every event.

Intervention groups

1

Description

Intervention group: Primary, secondary and tertiary interventions were designed based on specific target groups including schoolchildren, housewives, and high-risk persons. Officials of various sectors such as health, education, municipality, police, media, traders and community leaders were actively engaged as decision makers and collaborators. Interventional strategies were based on lifestyle modifications in diet, smoking and physical activity through face-to-face education, leaflets & brochures, school program alterations, training volunteers as health team and treating patients with NCD risk factors.

Category

empty

2

Description

Control group: routine health care

Category

empty

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Lipid and Glucose Study Unit

Full name of responsible person

Dr. A.A. Momenan

Street address

No. 320, 30-metri Nirooye Havai

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

research institute for endocrine sciences

Full name of responsible person

Prof. F. Azizi

Street address

No 24, Parvaneh Aven., Yaman St., Velenjak

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Grant name

مطالعه قند و لیپید تهران

Grant code / Reference number

750

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

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

TLGS unit

Full name of responsible person

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Position

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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