Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 heath 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

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Name of organization / entity

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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
City
tehran
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
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TLGS unit
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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