

Intervention phase of the Tehran Lipid and Glucose Study (TLGS phase II)

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
11/10/2008	No longer recruiting	<input checked="" type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
27/11/2008	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
20/11/2018	Other	

Plain English summary of protocol

Background and study aims

Noncommunicable disorders (NCDs) are long-term diseases that are not passed from person to person. NCDs include heart disease, cancer, lung disease and diabetes. This study is a long-term community-based programme which aims to evaluate lifestyle modification interventions to prevent or postpone the development of NCDs.

Who can participate?

Residents of District 13 of Tehran, aged 3 years and over

What does the study involve?

Participating areas are randomly allocated to either the intervention or the control group. Residents in the intervention areas receive interventions that aim to improve their lifestyle (e.g., diet, smoking and exercise) through education, leaflets, brochures, school programme alterations, and treating patients with NCD risk factors. Data is collected every 3 years to assess the effects of the different interventions on the prevalence of NCDs in the intervention areas as compared to the control areas, where residents do not receive the interventions.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Research Institute for Endocrine Sciences (Iran)

When is the study starting and how long is it expected to run for?

March 1999 to March 2020

Who is funding the study?

1. National Research Council, Ministry of Health (Iran)
2. Research Institute for Endocrine Sciences (Iran)

Who is the main contact?

Prof Fereidoun Azizi

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

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

Acronym

TLGS II

Study objectives

The Tehran Lipid and Glucose Study (TLGS) is a long term integrated community-based programme for prevention of non-communicable disorders (NCD) by development of a healthy lifestyle and reduction of NCD risk factors. The primary research goal is an evaluation of the feasibility and effectiveness of lifestyle modification interventions in preventing or postponing the development of NCD risk factors and outcomes in a population in nutrition transition. Secondary research goals include determining differences in the prevalence of major NCD risk factors and outcomes between intervention and control groups with special focus on angina pectoris, myocardial infarction, cerebrovascular events, diabetes mellitus, hypertension and dyslipidaemia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The National Research Council of the Islamic Republic of Iran (ref: 121); performed with the approval of the Human Research Review Committee of the Endocrine Research Centre, Shahid Beheshti University (MC).

Study design

Randomised community intervention (controlled field trial)

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Non-communicable diseases (NCD)

Interventions

Primary, secondary and tertiary interventions were designed based on specific target groups including school children, 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 and brochures, school programme alterations, training volunteers as health team and treating patients with NCD risk factors. Collection of demographic, clinical and laboratory data will be repeated every 3 years to assess the effects of different interventions in the intervention group as compared to control group.

Intervention Type

Behavioural

Primary outcome(s)

Major NCD risk factors including the following:

1. Glucose disorders (oral glucose tolerance test, fasting blood sugar)
2. Dyslipidaemia: serum total cholesterol, triglycerides, low density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C)
3. Obesity: a body mass index (BMI) of 25 to 29.9 kg/m² in adults is considered as overweight and a BMI equal to or more than 30 kg/m² is defined as obesity. Obesity and overweight in children and adolescents are defined according to international cut-off points for body mass index. Truncal obesity is defined as a waist-hip ratio (WHR) more than 0.95 in adult men and more than 0.8 in adult women.
4. Smoking, assessed by a 110-item questionnaire and Modifiable Activity Questionnaire (MAQ)
5. Hypertension (HTN)
6. Level of physical activity, assessed by a 110-item questionnaire and Modifiable Activity Questionnaire (MAQ)
7. Nutritional status, assessed by interviews

The primary outcomes are assessed every 3 years.

Key secondary outcome(s))

1. Any significant medical events
2. Mortality

The secondary outcomes are assessed annually.

Completion date

01/03/2020

Eligibility

Key inclusion criteria

1. Individuals aged 3 years and over, either sex
2. Residents of the District 13 of Tehran
3. Under the coverage of three medical health centres, selected using multistage cluster random sampling method
4. Agree for all members of each family, including those not having risk factors, to be enrolled

Participant type(s)

All

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

Mentally disabled persons

Date of first enrolment

01/03/1999

Date of final enrolment

01/03/2020

Locations

Countries of recruitment

Iran

Study participating centre

Research Institute for Endocrine Sciences

Tehran

Iran

19395-4763

Sponsor information

Organisation

Research Institute for Endocrine Sciences (Iran)

ROR

<https://ror.org/01kpm1136>

Funder(s)

Funder type

Government

Funder Name

National Research Council, Ministry of Health (Iran)

Funder Name

Research Institute for Endocrine Sciences (Iran)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2002		Yes	No
Results article	results	14/11/2007		Yes	No
Results article	assessment of alternative definitions results	01/05/2008		Yes	No

<u>Results article</u>	nested case control study results	05/06/2008	Yes	No
<u>Results article</u>	prospective study results	01/10/2008	Yes	No
<u>Results article</u>	anthropometric parameter results	01/11/2008	Yes	No
<u>Results article</u>	nutritional intervention results	01/11/2008	Yes	No
<u>Results article</u>	results	01/06/2010	Yes	No
<u>Results article</u>	results	01/02/2018	Yes	No
<u>Protocol article</u>	phase II protocol	25/01/2009	Yes	No
<u>Other publications</u>		15/06/2000	Yes	No
<u>Participant information sheet</u>	Participant information sheet	11/11/2025 11/11/2025	No	Yes
<u>Study website</u>	Study website	11/11/2025 11/11/2025	No	Yes