ISRCTN99959577 https://doi.org/10.1186/ISRCTN99959577

Latent autoimmune diabetes in the elderly

Submission date	Recruitment status	[ ] Prospectively registered
16/04/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/05/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/05/2018	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Type 2 diabetes is a common condition that causes the level of sugar (glucose) in the blood to become too high. The aim of this study is to find out whether autoantibodies currently thought to predict autoimmunity (an immune response of the body against its own healthy tissues) are present in type 2 diabetes patients.

Who can participate?
Patients with type 2 diabetes with onset over 65 years of age and a BMI under 30 kg/m2

What does the study involve?
Participants undergo height, weight, waist and blood pressure measurements. After a 12-h overnight fast, blood samples are taken to test for autoantibodies.

What are the possible benefits and risks of participating?
The study may lead to better treatment of type 2 diabetes. The study has no risks for the patients.

Where is the study run from?
1. Hospital Sirio Libanés (Argentina)
2. Buenos Aires University (Argentina)

When is the study starting and how long is it expected to run for?
March 2012 to February 2018

Who is funding the study?
University Institute of Health Sciences, Barcelo Foundation (Argentina)

Who is the main contact?
Prof. Gustavo Frechtel

Contact information

Type(s)
Scientific

Contact name
Prof Gustavo Frechtel

Contact details
Córdoba 2351
Buenos Aires City
Argentina
1413

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12446980

Study information

Scientific Title
Immunological and clinical characteristics of Latent Autoimmune Diabetes in the Elderly (LADE)

Acronym
LADE

Study objectives
Autoantibodies currently regarded to have predictive value for autoimmunity are present in T2DM patients with onset over 65 years of age and a BMI under 30 kg/m2.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee Hospital de Clínicas Universidad de Buenos Aires, 06/08/2012, ref: 12446980

Study design
Observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Autoimmune and non autoimmune type 2 diabetes mellitus

Interventions
155 T2DM patients were randomly recruited between June 2014 and March 2017 with two principal inclusion criteria: individuals with diabetes onset over 65 years of age and a BMI under 30 kg/m2.

Anthropometric measurements (height, weight and waist circumference), systolic blood pressure and diastolic blood pressure were determined by standardized protocols. BMI was calculated as weight (kg)/[height(m)]2. After a 12-h overnight fast, venous blood samples were obtained from every individual, centrifuged to obtain serum and analyzed immediately. Fasting plasma glucose (FPG), creatinine, total cholesterol, TG, LDL-C and HDL-C were determined in serum using standardized procedures by enzymatic methods. HbA1c was measured using high-performance liquid chromatography (HPLC) Variant II Turbo HbA1c Kit 2.0. GADA, IA2A and ZnT8A were assessed by radio ligand binding assay (RBA) as described.

Intervention Type
Other

Primary outcome measure
The prevalence of the autoantibodies GADA, IA2A and ZnT8A, assessed by radio ligand binding assay (RBA) at a single study visit

Secondary outcome measures
Measured at a single study visit:
1. HbA1c, measured using high-performance liquid chromatography (HPLC) Variant II Turbo HbA1c Kit 2.0
2. Cardiovascular disease prevalence, assessed using patients clinical records of coronary heart disease, stroke, or peripheral arterial disease
3. Fasting plasma glucose (FPG), creatinine, total cholesterol, TG, LDL-C and HDL-C, measured in serum using standardized procedures by enzymatic methods
4. BMI, calculated as weight (kg)/[height(m)]2
5. Anthropometric measurements (height, weight and waist circumference), systolic blood pressure and diastolic blood pressure, determined by standardized protocols

Overall study start date
30/03/2012

Completion date
15/02/2018

Eligibility

Key inclusion criteria
1. T2DM patients
2. Diabetes onset over 65 years of age
3. BMI under 30 kg/m2

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
155

Key exclusion criteria
1. Patients with active systemic disorders and/or infections
2. Individuals with a previous diagnosis of T1DM, liver or heart failure
3. Surgery or hospitalization over the past year

Date of first enrolment
01/06/2014

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
Argentina

Study participating centre
Hospital Sirio Libanés
Buenos Aires
1419

Study participating centre
Buenos Aires University
School of Pharmacy and Biochemistry
1413

Study participating centre

Buenos Aires University
Institute of Immunology, Genetics and Metabolism
Clinical Hospital and School of Pharmacy and Biochemistry
1413

Sponsor information

Organisation
Sirio Libanés Hospital

Sponsor details
Campana 4658
Buenos Aires
Argentina
1419
+54 (0)114574-4343
residencias@hospitalsiriolibanes.org

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
University/education

Funder Name
University Institute of Health Sciences, Barcelo Foundation

Results and Publications

Publication and dissemination plan
The trialists are planning a publication in a high-impact peer reviewed journal in the near future.

Intention to publish date
08/08/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Gustavo Frechtel.

IPD sharing plan summary

Available on request