# Latent autoimmune diabetes in the elderly

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

### 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