ISRCTN13159380 https://doi.org/10.1186/ISRCTN13159380

Use of alpha lipoic acid as a complementary treatment for the control of diabetes

Submission date
17/04/2017

Recruitment status
No longer recruiting

Registration date
10/05/2017

Overall study status
Completed

Last Edited
26/11/2020

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (T2DM) is a long term condition where a person is unable to control their blood sugar (glucose) levels as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). If not properly controlled, T2DM can lead to a range of complications, such as irreversible damage to the kidneys, eyes and nerves. This is thought to occur because high blood sugar levels leads to an increase of free radicals, which cause irreversible damage to the body's cells (oxidative stress). Antioxidants are substances which are able to essentially "neutralize" free radicals in the body, and can be found in a range of vitamins and minerals. Alpha lipoic acid (ALA) is a naturally occurring antioxidant made in the body, which helps to support cellular processes. Recent studies have suggested that taking ALA supplements could be an effective way of treating long-term conditions such as diabetes by reducing oxidative stress. The aim of this study is to evaluate the effects of ALA supplements on oxidative stress and blood sugar control in diabetic older adults.

Who can participate?
Adults aged 60-74 who have been diagnosed with T2DM.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are asked to take two capsules that contain ALA every day for 12 months. Those in the second group are asked to take two capsules that contain a placebo (dummy drug) every day for 12 months. At the start of the study and then after six and 12 months, participants in both groups have their blood pressure measured using an automated blood pressure cuff and have blood samples taken to assess levels of oxidative stress and how well they are controlling their blood sugar levels.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
1. University health care clinic “Zaragoza” (Mexico)
2. Gerontology Research Unit of “Facultad de Estudios Superiores Zaragoza, UNAM” (Mexico)
3. Institute of Social Security and Services of State Workers (ISSSTE) “Ignacio Zaragoza” (Mexico)

When is the study starting and how long is it expected to run for?
September 2014 to October 2017

Who is funding the study?
National Autonomous University of Mexico (Mexico)

Who is the main contact?
Dr Víctor Manuel Mendoza-Nuñez

Contact information

Type(s)
Scientific

Contact name
Dr Víctor Manuel Mendoza Nuñez

ORCID ID
http://orcid.org/0000-0002-9137-3405

Contact details
Avenida Universidad # 3000
Ciudad Universitaria
Delegación Coyoacán
CDMX
Mexico City
Mexico
04510

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IN222015

Study information

Scientific Title
Effect of alpha lipoic acid on glycemic control, oxidative stress and inflammation markers in older adults with type 2 diabetes mellitus

Study objectives
According to scientific evidence about hypoglycemic effect of alpha lipoic acid, diabetic patients who will receive this compound will show improvement on glycemic control and will avoid complications due to T2DM.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bioethics and Biosafety Committee of the Research Committee of “Facultad de Estudios Superiores Zaragoza, UNAM”, 12/01/2015, ref: 25/11/SO/3.4.3

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions
Following provision of informed consent, participants are randomised to one of two groups. At baseline, blood samples will be taken to assess levels of oxidative stress, inflammation and glycemic control.

Intervention group: Participants take two capsules containing 300 mg of ALA daily for 12 months

Control group: Participants take two capsules containing a placebo daily for 12 months

After 6 and 12 months, the initial blood tests are repeated to evaluate whether there has been an improvement in those in the group that received ALA.

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
ALA

Primary outcome measure
1. Oxidative stress is assessed by measuring the levels of SOD, GPx, TAS, TBARS and isoprostane markers measured in blood and plasma by spectrophotometry and ELISA, respectively, at baseline, 6 and 12 months
2. Inflammation is assessed by measuring serum levels of TNF-α, IL-1β, IL-6, IL-8, IL-1, IL-12p70 by flow cytometry and PCR by turbidimetry at baseline, 6 and 12 months
3. Glycemic control is assessed by measuring HbA1c by turbidimetry and RAGE by ELISA, at baseline, 6 and 12 months

Secondary outcome measures
1. Serum glucose levels and the lipid profile determined by spectrophometry, both performed in serum at the beginning of the study, 6 and 12 months
2. Blood pressure was measured using mercury sphygmomanometer, at baseline, 6 and 12 months

Overall study start date
06/09/2014

Completion date
01/10/2017

Eligibility

Key inclusion criteria
1. Aged 60 to 74 years old
2. Diagnosed with T2DM
3. No renal damage
4. Provision of informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Total final enrolment
135

Key exclusion criteria

1. People who have taken antioxidant supplements or anti-inflammatory drugs in the last 6 month
2. With hypothyroidism
3. Who presenting problems of digestive tract absorption or have been submitted to gastric surgery
4. With liver failure
5. Hypersensitivity to ALA

Date of first enrolment
01/08/2016

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Mexico

Study participating centre
University health care clinic "Zaragoza"
Guelatao # 66 Colonia Ejército de Oriente Delegación Iztapalapa
Mexico City
Mexico
09230

Study participating centre
Gerontology Research Unit of "Facultad de Estudios Superiores Zaragoza, UNAM"
Batalla 5 de Mayo SN, Ejèrcito de Oriente, Delegación Iztapalapa
Mexico City
Mexico
09230

Study participating centre
Institute of Social Security and Services of State Workers (ISSSTE) "Ignacio Zaragoza"
Calzada Ignacio Zaragoza #1711, Chinampac de Juárez, Delegación Iztapalapa
Mexico City
Mexico
09208

Sponsor information

Organisation
National Autonomous University of Mexico

Sponsor details
J.C. Bonilla 66
Ejercito de Oriente
Delegación Iztapalapa
Mexico City
Mexico
09230
+52 562 307 21
mendovic@servidor.unam.mx

Sponsor type
University/education

Website
http://www.zaragoza.unam.mx/

ROR
https://ror.org/01tmp8f25

Funder(s)

Funder type
University/education

Funder Name
National Autonomous University of Mexico

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal in 2018.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/06/2019	26/11/2020	Yes	No