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The impact of lipoic acid and alpha-tocopherol supplementation in patients with type 2 diabetes mellitus

Submission date 16/06/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/08/2010	**Overall study status** Completed	
Last Edited 12/08/2010	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The impact of alpha-lipoic acid and alpha-tocopherol supplementation in the control of insulin resistance and other metabolic syndrome components in patients with type 2 diabetes mellitus: A double-blind, randomised, placebo-controlled trial

Acronym
ALA and ATO in patients with DM2

Study objectives
If the introduction of combined antioxidant alpha-lipoic acid (ALA) and alpha-tocopherol (ATO) modifies the components of the Metabolic Syndrome in patients with type-2 Diabetes mellitus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The local ethics committee approved on the 19th of August 2004 (ref:128/04)

Study design
Randomised double blind placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Diabetes mellitus type II (DM2)

Interventions
One or two types of antioxidants or placebo for a period of four months (16 weeks)
1. 28 patients received a supplement consisting of 600 mg / day of lipoic acid and 800 mg / day of vitamin E
2. 28 patients received a supplement consisting of 600 mg / day of lipoic acid
3. 28 patients received a supplement consisting of 800 mg / day of vitamin E
4. 28 patients received placebo

Intervention Type
Other

Phase
Phase IV

Primary outcome measure
Assessing the impact of supplemental antioxidants vitamin E and lipoic acid in the indicators of metabolic syndrome in patients with DM2.
All outcomes were measured at baseline and post-treatment (i.e. 16 weeks)

Secondary outcome measures
1. Assessing the impact of combined supplementation of antioxidants alone and in insulin resistance, as detected by the method HOMA (Homeostasis Model Assessment) in patients with DM2
2. Determine the serum levels of vitamin E in patients with DM2 before and after supplementation with antioxidants
3. To evaluate the effect of supplementation with antioxidants in the biochemical indicators of MS patients with DM2 before and after the intervention
4. To evaluate anthropometric measurements before and after supplementation with antioxidants
All outcomes were measured at baseline and post-treatment (i.e. 16 weeks)

Overall study start date
01/09/2005

Completion date
28/02/2006

Eligibility

Key inclusion criteria
1. Aged 38-75 years
2. Patients with type II diabetes mellitus (DM2)
3. Registered in the Integrated Health Center (NIS) and Polyclinics in Jundiai, Brazil
4. At least two years of disease diagnosis
5. Without the presence of episodes of cetocidose and A1c less than 9.0% (data from the last examination until four months before the screening)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
102

Key exclusion criteria

1. Insulin therapy at baseline or in the segment of the research
2. Taking vitamin supplements with lipoic acid and/or vitamin E in the formulation
3. Pregnant status or become pregnant during the study
4. Smokers consuming more than 10 cigarettes/day
5. Daily intake alcoholic beverages
6. Presence of renal and/or cardiovascular disease
7. DM2 decompensation due to infection
8. Change or introduction of new medication
9. Family history of autoimmune disease

Date of first enrolment
01/09/2005

Date of final enrolment
28/02/2006

Locations

Countries of recruitment
Brazil

Study participating centre
Av Dr Arnaldo, 715
São PAulo
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Sponsor information

Organisation
State of São Paulo Research Foundation (FAPESP) (Brazil)

Sponsor details
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Sponsor type
University/education

ROR

https://ror.org/02ddkpn78

Funder(s)

Funder type
Research organisation

Funder Name
State of São Paulo Research Foundation (FAPESP) (Brazil) (ref: 04/04108-1)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration