ISRCTN20939990 https://doi.org/10.1186/ISRCTN20939990

Protective effect of α-Lipoic Acid on the Early stage of Diabetic Nephropathy

Submission date	Recruitment status	[_] Prospectively registered
16/08/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/09/2013	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
09/09/2013	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
We are carrying out a study to investigate the effects of α-lipoic acid (α-LA) in early diabetic nephropathy (kidney disease in diabetic patients). Our goal is to evaluate the protective effects of α-LA on the vascular endothelium function (blood circulation) through improving the oxidative stress in early diabetic nephropathy patients. We want to compare a series of clinical biochemical markers, particularly flow-mediated dilation (FMD), within the two different groups. The study's findings should boost the administration of α-LA in the treatment for early diabetic nephropathy.

Who can participate?
The study aims to recruit about 62 early diabetic nephropathy patients with type 2 diabetes.

What does the study involve?
Over a period of two weeks participants will be randomly allocated to receive either a regular therapy strategy or α-LA plus regular therapy. At the screening, we will collect blood samples or measure the basal flow-mediated dilation (FMD) value, and after the 14-day treatment interval corresponding samples and measurements will be collected and tested.

What are the possible benefits and risks of participating?
The results of the study are likely to confirm α-LA as a potent anti-oxidative agent that could protect susceptible kidney cells from oxidative damage.
There will be no immediate direct risk of administration of α-LA in the treatment of early diabetic nephropathy.

Where is the study run from?
The study has been set up by the Wuxi No.2 Peoples Hospital, China.

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start in January 2011. Participants will be enrolled on the study for a period of about two weeks; however, the study will extend beyond this as we intend to look at participants health over several months to assist future studies about α-LA administration in early diabetic nephropathy.

Who is funding the study?
Funding has been provided by Wuxi No.2 Peoples Hospital, China.

Who is the main contact?
Ph.D. Huiming Sheng, Immune1004@gmail.com
Professor. Weifeng Yao, yaowf68@sohu.com

Contact information

Type(s)
Scientific

Contact name
Dr Huiming Sheng

Contact details
68 Zhongshan road
wuxi
China
214002

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Protective effect of α-Lipoic Acid on the Early stage of Diabetic Nephropathy via reducing oxidative stress and improving vascular endothelium function

Acronym
LAEDN

Study objectives
Protective effect of α-Lipoic Acid on the early stage of diabetic nephropathy via reducing oxidative stress and improving vascular endothelium function.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethical Committee of the Wuxi No.2 Hospital, 18 Dec 2011

Study design
Two groups randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

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
Early stage of diabetic nephropathy

Interventions
The study subjects were divided into two groups randomly, control group and therapy group. Both control and therapeutic group subjects received regular hypoglycemic therapy and strict diabetes diet, moreover, during the treatment, no antiplatelet, anticoagulants, vascular dilation, lipid-lowering and Angiotensin-Converting Enzyme Inhibitors(ACEI) drugs were administered. In addition, α-lipoic acid (Alpha-Lipon®, Eisai China Inc.) was given intravenously with 600 mg/day, for 2 weeks for therapeutic group only.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
α-Lipoic Acid

Primary outcome measure
Fasting venous blood and total 24-hour urine samples were collected before and after the treatment, subsequently glucose, triglyceride (TG), total cholesterol (TC), low density lipoprotein (LDL-C), high density lipoprotein (HDL-C) and serum creatine (SCr) were detected by the automatic biochemical analyzer . urinary albumin excretion rates (UAER) was evaluated by radioimmunoassay kit , the content of malondialdehyde (MDA) was assayed by thiobarbituric acid, and the activities of Superoxide Dismutase (SOD) was measured by spectro -photometer assays.

Laboratory tests including GLU, TG, TC, LDL-C, HDL-C, SCr, were performed at screening, and the second day post the 14-day treatment freshly by the automatic biochemical analyzer. Simultaneously, UAER, MDA and SOD were performed one-time according to the manuals. The samples were collected at the same time points as above and stored in -80, subsequently thawed and analyzed at the same time.

Secondary outcome measures
Endothelium-dependent vasodilator functionreferred to brachial arterial flow-mediated dilation (FMD). FMD was measured at screening day and in 48h post the treatment, moreover the time point of test and patient physical position considered.

Overall study start date
01/01/2011

Completion date
30/12/2013

Eligibility

Key inclusion criteria
1. The diagnosis of diabetic mellitus was based on the guideline of World Health Organization (WHO)
2. Three consecutive 30mg/24h< Urinary Albumin Excretion Rate (UAER)<200mg/24h during the recent 1 month with normal renal function (serum Cr≤133μmol/L, BUN≤7.1mmol/L)
3. Fasting blood glucose<7.0mmol/L, postprandial blood glucose<10mmol/L, and with stable blood pressure within the range of 140160mmHg/85100mmHg.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
62

Key exclusion criteria
1. No obvious symptoms of cardio-cerebrovascular and liver disease, and no recent ketoacidosis, hyperosmotic nonketonic coma , lactic acidosis and no other acute complications.
2. No hyperthyroidism, concurrent infection and other renal disorders
3. No anti-oxidative or nephrotoxic drugs in the recent one month

Date of first enrolment
01/01/2011

Date of final enrolment

30/12/2013

Locations

Countries of recruitment
China

Study participating centre
68 Zhongshan road
wuxi
China
214002

Sponsor information

Organisation
Wuxi No. 2 People's Hospital (China)

Sponsor details
68 Zhongshan road
wuxi
China
214002

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0399zkh42

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Wuxi No. 2 People's Hospital (China) - pilot funding

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