# Protective effect of $\alpha$ -Lipoic Acid on the Early stage of Diabetic Nephropathy

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

## Plain English summary of protocol

Background and study aims

We are carrying out a study to investigate the effects of  $\alpha$ -lipoic acid ( $\alpha$ -LA) in early diabetic nephropathy (kidney disease in diabetic patients). Our goal is to evaluate the protective effects of  $\alpha$ -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  $\alpha$ -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  $\alpha$ -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  $\alpha$ -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  $\alpha$ -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  $\alpha$ -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

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

#### Scientific Title

Protective effect of  $\alpha$ -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  $\alpha$ -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 $\leq$ 133 $\mu$ mol/L, BUN $\leq$ 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

# 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