Effects of combination of lipoic acid and pyridoxine on albuminuria, serum advanced glycated end products and vascular inflammatory factors in patients with diabetic nephropathy

Protocol summary

Summary
The aim of this double-blind randomized clinical trial study was to determine the effects of combination of lipoic acid and pyridoxine on albuminuria, serum advanced glycated end products and vascular inflammatory factors in patients with diabetic nephropathy. Thirty-four patients from Taleghani hospital were randomly assigned to either supplement or placebo group. The patients in supplement group received 800 mg lipoic acid (as 2 capsules) and 80 mg pyridoxine (as 2 tablets) daily for 12 weeks, while the placebo group received corresponding placebos. At the baseline and the end of week 12, a urine sample and 10 ml blood was collected from each patient after a 12-14-hours fasting and urinary albumin, serum pentosidine, carboxymethyl lysine, malondialdehyde, endothelin-1, nitric oxide, glucose, glycosylated hemoglobin, vascular and systemic inflammation markers, and also systolic and diastolic blood pressures were measured.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT138808252716N1
Registration date: 2010-01-10, 1388/10/20
Registration timing: retrospective

Recruitment status
Recruitment complete

Funding source
National Nutrition and Food Technology Research Institute

Expected recruitment start date
2009-01-10, 1387/10/21
Expected recruitment end date
2009-12-20, 1388/09/29
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of combination of lipoic acid and pyridoxine on albuminuria, serum advanced glycated end products and vascular inflammatory factors in patients with diabetic nephropathy

Public title
Effects of combination of lipoic acid and pyridoxine on albuminuria, serum advanced glycated end products and vascular inflammatory factors in patients with diabetic nephropathy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: Presence of Diabetic Nephropathy
Exclusion Criteria: Chronic kidney disease, Infections, Inflammatory diseases, Receiving anti-inflammatory drugs, Vitamins B6, E, C, and Lipoic acid supplement

Age
From 18 years old to 75 years old

Gender
Both

Phase
N/A

Groups that have been masked
### Sample size
- Target sample size: **34**

### Randomization (investigator's opinion)
- **Randomized**

### Randomization description
- **Double blinded**

### Blinding (investigator's opinion)
- **Double blinded**

### Blinding description
- **Placebo**
  - **Used**

### Assignment
- **Parallel**

### Other design features
- **Secondary Ids**
  - **empty**

### Ethics committees

<table>
<thead>
<tr>
<th>ID</th>
<th>Ethics committee</th>
</tr>
</thead>
</table>
| 1  | **Name of ethics committee**  
National Nutrition and Food Technology Research Institute  
**Street address**  
West Arghavan St., Farahzadi Blv., Shahrak Qods  
**City**  
Tehran  
**Postal code**  
Approval date: 2009-01-03, 1387/10/14  
**Ethics committee reference number**  
P/25/47/6253 |

### Health conditions studied

| ID | Description of health condition studied  
Diabetic Nephropathy  
**ICD-10 code**  
N08.3*  
**ICD-10 code description**  
Glomerular disorders in diabetes mellitus |

### Primary outcomes

| ID | Description  
Microalbuminuria  
**Timepoint**  
Baseline and Week 12  
**Method of measurement**  
ELISA |

### Secondary outcomes

| ID | Description  
Hb A1c  
**Timepoint**  
Baseline and Week 12  
**Method of measurement**  
Ion Exchange Chromatography |

| ID | Description  
serum MDA, NO, Glucose  
**Timepoint**  
Baseline and Week 12  
**Method of measurement**  
Colorimetry |

| ID | Description  
Systolic and diastolic blood pressure  
**Timepoint**  
Baseline and Week 12  
**Method of measurement**  
Mercury Sphygmomanometer |

| ID | Description  
Serum pentosidine, carboxymethyl lysine, hs-CRP, IL-6, sICAM-1, sVCAM-1, sE-selectin, Endothelin-1  
**Timepoint**  
Baseline and Week 12  
**Method of measurement**  
ELISA |

### Intervention groups

| ID | Description  
800 mg lipoic acid placebo (as 2 capsules) and 80 mg pyridoxine placebo (as 2 tablets) daily for 12 weeks  
**Category**  
Placebo |

| ID | Description  
800 mg lipoic acid (as 2 capsules)and 80 mg pyridoxine (as 2 tablets) daily for 12 weeks  
**Category**  
Treatment - Drugs |

### Recruitment centers

| ID | Recruitment center |
Name of recruitment center
Taleghani hospital

Full name of responsible person
Dr. Hadi Tabibi

Street address
Velenjak St, next to shahid Beheshti University of Medical Sciences

City
Tehran

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
National Nutrition and Food Technology Research Institute

Full name of responsible person
Dr. Esmat Naseri

Street address
46, West Arghavan St., Farahzadi Blv., Shahrak Qods,
City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
National Nutrition and Food Technology Research Institute

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin
empty

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Department of Human Nutrition, Faculty of Nutrition and Food Technology, National Nutrition and Food

Full name of responsible person
Dr. Hadi Tabibi

Position
Assistant Professor

Other areas of specialty/work

Street address
46, West Arghavan St., Farahzadi Blv., Shahrak Qods

City
Tehran

Postal code

Phone

Fax

Email
hadtabibi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Department of Human Nutrition, Faculty of Nutrition and Food Technology, National Nutrition and Food

Full name of responsible person
Dr. Hadi Tabibi

Position
Assistant Professor

Other areas of specialty/work

Street address
46, West Arghavan St., Farahzadi Blv., Shahrak Qods

City
Tehran

Postal code

Phone
+98 21 2236 0656

Fax

Email
hadtabibi@yahoo.com

Web page address

Person responsible for updating data

Contact
Name of organization / entity
Department of Human Nutrition, Faculty of Nutrition Sciences and Food Technology, National Nutrition and Food

Full name of responsible person
Dr. Hadi Tabibi

Position
Assistant Professor

Other areas of specialty/work

Street address
46, West Arghavan St., Farahzadi Blv., Shahrak Qods

City
Tehran

Postal code

Phone

Fax

Email
hadtabibi@yahoo.com

Web page address

Sharing plan
Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report