Effect of angiotensin-converting enzyme inhibitors on systemic inflammation and myocardial sympathetic innervation in normotensive patients with type two diabetes mellitus

Submission date	Recruitment status	Prospectively registered
21/05/2007	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
12/06/2007	Completed	[X] Results
Last Edited	Condition category	Individual participant data
25/10/2021	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Panos Vardas

Contact details

Heraklion University Hospital Stavrakia & Voutes Heraklion Greece 71409 +30 2810 375 026 cardio@med.uoc.gr

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Effect of angiotensin-converting enzyme inhibitors on systemic inflammation and myocardial sympathetic innervation in normotensive patients with type two diabetes mellitus

Study objectives

Diabetes Mellitus (DM) may cause an increase in the inflammatory status and oxidative stress as well as sympathetic nervous system overactivity, even in the absence of any other organic heart disease. We investigate the effect of perindopril, an Angiotensin-Converting Enzyme inhibitor (ACE-i), on indexes of systemic inflammation and oxidative stress in normotensive patients with type two DM. We also examine the effect of the drug on the disturbances of left ventricular myocardial adrenergic innervation that may be seen in these patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The ethics committee of Heraklion University Hospital approved the study on the 23rd May 2004 (ref: 4048/20-4-04).

Study design

The patients were randomised to 4 mg perindopril or placebo in an open-label, parallel-group, randomised design.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Type two Diabetes Mellitus (DM)

Interventions

The patients were randomly allocated by a computer algorithm to one of two groups for treatment with 4 mg perindopril per os or placebo for six months, in an open-label, parallel-group, randomised design.

Patients were required to visit the outpatients clinic one month, three months and six months after the initiation of treatment.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Angiotensin-converting enzyme inhibitor (perindopril)

Primary outcome measure

Evaluation of total peroxides, interleukin-6 and a tumour necrosis factor-alpha were performed before and six months after the initiation of treatment.

Secondary outcome measures

Assessment of cardiac adrenergic innervation before and after perindopril treatment.

Overall study start date

12/12/2005

Completion date

25/06/2008

Eligibility

Key inclusion criteria

The study population was recruited from the Cardiology Outpatients Department. All participants:

- 1. Had type two DM (World Health Organisation criteria)
- 2. Were diagnosed at an age over 30 years
- 3. Had DM controlled by diet or blood glucose-lowering agents for at least six months
- 4. Were normotensive (Blood Pressure [BP] less than 130/85 mmHg)
- 5. Had no indications of other organic heart disease

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Total final enrolment

62

Key exclusion criteria

- 1. Heavy smokers
- 2. Pregnant or lactating women
- 3. Type one DM or secondary diabetes
- 4. Previous or ongoing treatment with ACE-i, angiotensin receptor blockers, antioxidant or immunosuppressive agents
- 5. Systolic BP less than 100 mmHg or diastolic BP less than 50 mmHg
- 6. Poor glycaemic control
- 7. Hyperuricaemia
- 8. Previous history or medication for hypertension, cerebrovascular, liver or renal disease
- 9. Serum potassium more than 5 mEq/L
- 10. Albumin excretion rate more than 200 µg/min
- 11. History of drug or alcohol abuse
- 12. Any chronic inflammatory or other infectious disease during the last six months
- 13. Uncontrolled hypothyroidism

Date of first enrolment

12/12/2005

Date of final enrolment

25/06/2008

Locations

Countries of recruitment

Greece

Study participating centre Heraklion University Hospital

Heraklion Greece 71409

Sponsor information

Organisation

Heraklion University Hospital (Greece)

Sponsor details

Cardiology Department Stavrakia & Voutes Heraklion Greece 71409 +30 2810 375 026 cardio@ymed.uoc.gr

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/0312m2266

Funder(s)

Funder type

University/education

Funder Name

University of Crete School of Medicine (Greece)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results article29/11/200725/10/2021YesNo