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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
21/05/2007	No longer recruiting
Registration date	**Overall study status**
12/06/2007	Completed
Last Edited	**Condition category**
25/10/2021	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
Assessment of cardiac adrenergic innervation before and after perindopril treatment.

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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)

ROR
https://ror.org/0312m2266

Funder(s)

Funder type
University/education

Funder Name
University of Crete School of Medicine (Greece)

Results and Publications

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 type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/11/2007	25/10/2021	Yes	No