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Multi-centre randomised double blind parallel group study: enalapril vs nifedipine vs placebo in diabetic patients

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
24/10/2019

Condition category
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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0010

Study information

Scientific Title
Multi-centre randomised double blind parallel group study: enalapril vs nifedipine vs placebo in diabetic patients

Acronym
ESPRIT

Study objectives
A multi-centre randomised double blind parallel group study evaluating the efficacy of Enalapril and Nifedipine retard and placebo on the evolution of the renal glomerular lesions of diabetic patients with increased urinary albumin excretion. To determine whether Enalapril (an ACE inhibitor) preferentially halts or reverses the progression of the glomerular lesions of diabetic nephropathy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre randomised controlled double-blind parallel group study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Nutritional, metabolic and endocrine diseases: Diabetes

Interventions
Enalapril and nifedipine retard versus placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Enalapril and Nifedipine retard

Primary outcome measure
Whether Enalapril (an ACE inhibitor) preferentially halts or reverses the progression of the glomerular lesions of diabetic nephropathy.

Secondary outcome measures
Not provided at time of registration

Overall study start date
04/01/1993

Completion date
31/03/1996

Eligibility

Key inclusion criteria
Diabetic patients with increased urinary albumin excretion

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
04/01/1993

Date of final enrolment
31/03/1996

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
South Cleveland Hospital
Middlesborough
United Kingdom
TS4 3BW

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	ESPRIT publications	01/02/2000		Yes	No
Results article	results	01/04/2001	24/10/2019	Yes	No