

# 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

☒ Results

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

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**Contact details**

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## Additional identifiers

**Protocol serial number**

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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

31/03/1996

## Eligibility

**Key inclusion criteria**

Diabetic patients with increased urinary albumin excretion

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

South Cleveland Hospital

Middlesborough

United Kingdom

TS4 3BW

## Sponsor information

**Organisation**

## Funder(s)

### Funder type

Government

### Funder Name

NHS Executive Northern and Yorkshire (UK)

## Results and Publications

### 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? |
|------------------------------------|---------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>    | results             | 01/04/2001   | 24/10/2019 | Yes            | No              |
| <a href="#">Other publications</a> | ESPRIT publications | 01/02/2000   |            | Yes            | No              |