Protection Against Nephropathy in Diabetes with Atorvastatin

Submission date	Recruitment status No longer recruiting	Prospectively registeredProtocol		
14/02/2008				
Registration date	Overall study status	Statistical analysis plan		
21/04/2008	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
23/07/2019	Nutritional, Metabolic, Endocrine			

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

N/A

Study information

Scientific Title

Protection Against Nephropathy in Diabetes with Atorvastatin

Acronym

PANDA

Study objectives

To compare the effect of treatment with a low and high dose HMG CoA reductase inhibitor on the progression of diabetic nephropathy in patients with type II diabetes whose blood pressure will be controlled using antihypertensive regimens that will include angiotensin II receptor antagonists.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Central Manchester Research Ethics Committee. Date of approval: 28/07/2004 (ref: 04/Q1407/51)

Study design

A double-blinded parallel study, randomised by block design and stratified by centre.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Type II diabetes with proteinuria

Interventions

1 x 10 mg active atorvastatin (oral) and 2 x 40 mg placebo vs 2 x 40 mg active atorvastatin (oral) and 1 x 10 mg placebo for three years.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Atorvastatin

Primary outcome(s)

- 1. Difference in the mean level of glomerular filtration rates at 3 years follow-up between patients receiving atorvastatin 10 mg and 80 mg daily
- 2. Difference in the mean level of albumin excretion rates at 3 years follow-up between patients receiving atorvastatin 10 mg and 80 mg daily

Key secondary outcome(s))

1. Change in serum creatinine and GFR between baseline and 3 years follow-up for patients receiving atorvastatin 10 mg and 80 mg daily

- 2. Difference in the mean level of serum creatinine at 3 years follow-up between patients receiving atorvastatin 10 mg and 80 mg daily
- 3. Difference in the percentage of patients achieving low density lipoprotein (LDL) cholesterol levels <2.6 mmol/l at 3 years follow-up between patients receiving atorvastatin 10 mg and 80 mg daily
- 4. Difference in the percentage of patients who have a cardiovascular event defined as documented non fatal acute myocardial infarction, hospital admission for unstable angina, appearance of new Q waves on electrocardiogram (ECG), coronary heart disease (CHD) death, coronary artery bypass surgery, coronary angioplasty/stenting or lower limb revascularisation, ischaemic stroke shown by abnormal brain scan or permanent neurological deficit, amputation 5. Difference in the percentage of patients who need photocoagulation for diabetic retinopathy within the first 3 years of follow-up between patients receiving atorvastatin 10 mg and 80 mg daily

Completion date

30/06/2008

Eligibility

Key inclusion criteria

- 1. Type 2 diabetes (defined according to the World Health Organization criteria) previously known to have proteinuria or microalbuminuria
- 2. Urinary albumin:creatinine ratio greater than 5 mg/mmol on two consecutive urine samples
- 3. Aged over 40
- 4. Capable of giving informed consent
- 5. Consent to inform General Practitioner of inclusion in study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

119

Key exclusion criteria

- 1. Urinary protein output >2q/24 hours
- 2. Serum creatinine >= 200 µmol/l
- 3. Blood pressure >160/90 mmHg at randomisation
- 4. Women of child bearing potential
- 5. Serum cholesterol >= 7 mmol/l or fasting serum triglycerides >= 6 mmol/l at any visit
- 6. Taking >10 mg of atorvastatin at screening
- 7. Untreated hypothyroidism

- 8. Hepatic dysfunction, transaminase >2 times the upper limit of normal or alkaline phosphatase >1.5 times the upper limit of normal
- 9. Any other concomitant illness other than diabetes or its complication likely to effect outcome 10. Concomitant medication that may interact adversely with HMG-CoA reductase inhibitors or ATII receptor antagonists
- 11. Known intolerance of ATII receptor antagonists or HMG-CoA reductase inhibitors
- 12. HbA1c > 10% at randomisation
- 13. Current participation in another clinical trial
- 14. Unable to comply with protocol for other reasons
- 15. Other lipid lowering medication at randomisation

Date of first enrolment

19/11/2004

Date of final enrolment

30/06/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Division of Cardiovascular and Endocrine Science

Manchester United Kingdom M13 9NT

Sponsor information

Organisation

University of Manchester (UK)

ROR

https://ror.org/027m9bs27

Funder(s)

Funder type

Industry

Funder Name

Pfizer UK Ltd (UK)

Funder Name

University of Manchester (Grant ref: R011264) (UK)

Alternative Name(s)

The University of Manchester, University of Manchester UK, University of Manchester in United Kingdom, UoM

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

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?
Results article	results	01/01/2011		Yes	No
Results article	results	01/01/2018	23/07/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes