

Protection Against Nephropathy in Diabetes with Atorvastatin

Submission date 14/02/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/04/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/07/2019	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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
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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

19/11/2004

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

Age group

Adult

Sex

Both

Target number of participants

200

Total final enrolment

119

Key exclusion criteria

1. Urinary protein output >2g/24 hours
2. Serum creatinine $\geq 200 \mu\text{mol/l}$
3. Blood pressure >160/90 mmHg at randomisation
4. Women of child bearing potential
5. Serum cholesterol $\geq 7 \text{ mmol/l}$ or fasting serum triglycerides $\geq 6 \text{ mmol/l}$ 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**

England

United Kingdom

Study participating centre

Division of Cardiovascular and Endocrine Science

Manchester

United Kingdom

M13 9NT

Sponsor information

Organisation

University of Manchester (UK)

Sponsor details

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Sponsor type

University/education

Website

<http://www.manchester.ac.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

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?
Results article	results	01/01/2011		Yes	No
Results article	results	01/01/2018	23/07/2019	Yes	No