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Protection Against Nephropathy in Diabetes with Atorvastatin

Submission date	Recruitment status
14/02/2008	No longer recruiting
Registration date	**Overall study status**
21/04/2008	Completed
Last Edited	**Condition category**
23/07/2019	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

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)

Primary study design
Interventional

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

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 >2g/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
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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)
University of Manchester in United Kingdom, University of Manchester UK, The University of Manchester, 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