

Effect of beta blockers on haemodynamics and brain natriuretic peptide (BNP)

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/09/2008	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ian B Wilkinson

Contact details
Clinical Pharmacology Unit
Level 3, ACCI
Box 110
Addenbrooke's NHS Trust
Cambridge
United Kingdom
CB2 2QQ
+44 01223-336806
ibw20@cam.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0544112292

Study information

Scientific Title

Study objectives

Do different beta blockers have variant effects on arterial stiffness and central blood pressure?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Cardiovascular: Hypertension

Interventions

The aim of the study is to test the effects of Atenolol, Pindolol and Nebivolol on central blood pressure and augmentation index. Studies of normotensive and hypertensive individuals have confirmed that pulse pressure is a better predictor of cardiovascular events than mean pressure in older adults.

There is evidence that the traditional beta blocker Atenolol is less effective in reducing strokes and also lowering central blood pressure and augmentation index. This may be due to a direct arterial stiffening effect but also partly due to a fall in heart rate. However, Nebivolol is much more beta 1 selective than Atenolol and also causes vasodilatation by releasing NO which may in turn have additional benefits with regard to augmentation index and central blood pressure.

At visit 1 there will be a physical examination, blood pressure measurements, blood tests and measurements of arterial stiffness using a small sensor placed in turn against the skin on the arm and neck. The patients will be asked about their general medical history to ensure that it is safe for them to take part in the study.

Patients will be randomised prior to commencement. Patients will then be given a single dose of either Atenolol 50 mg, Nebivolol 5 mg, Pindolol 5 mg, a placebo. Repeat measurements will be taken after 1, 2 and 4 h.

Patients will return 1 week later for visit 2 when repeat measurements as for visit 1 will be performed and different medication given. As at visit 1 measurements will be taken after 1, 2 and 4 h.

Patients will then be asked to return for visits 3 and 4 after an interval of 1 week between each visit. All measurements as for visit 1 and 2 will be repeated and randomised medication given.

Each visit will last for approximately 5 h.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

14/05/2002

Completion date

13/05/2005

Eligibility

Key inclusion criteria

20 subjects in the age range of 18-55 years.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

55 Years

Sex

Not Specified

Target number of participants

20

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

14/05/2002

Date of final enrolment

13/05/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Clinical Pharmacology Unit

Cambridge

United Kingdom

CB2 2QQ

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

Cambridge Consortium - Addenbrooke's (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