

A study investigating the effects of sitagliptin on heart muscle performance in patients with heart disease and diabetes

Submission date 15/05/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/07/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/01/2010	Condition category Circulatory System	<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
2008-000300-89

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

EudraCT: 2008-000300-89; DSSita-01

Study information

Scientific Title

The effects of sitagliptin (Januvia®) on myocardial performance in patients with coronary artery disease

Study objectives

In patients with insulin resistance (independent of type two diabetes mellitus) and coronary disease, sitagliptin will promote myocardial glucose utilisation and protect the heart against post-ischaemic left ventricular dysfunction and improve the myocardial response to dobutamine stress.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Cambridge Research Ethics Committee 2 on the 1st May 2008 (ref: 08/H0304/22).

Study design

Single centre, interventional, open trial

Primary study design

Interventional

Secondary study design

Non 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

Coronary artery disease

Interventions

Subjects undergo two dobutamine stress echoes (DSE) (which last about half an hour) one week apart. Before the control DSE they are given a 75 g solution of glucose to drink. Before the other DSE they are given a single, oral dose of 100 mg of sitagliptin (Januvia®) and a 75 g oral glucose solution. A number of different DSE measurements are then compared between the two scans.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Sitagliptin (Januvia®)

Primary outcome measure

LV performance during dobutamine stress echocardiography (wall motion scoring and ejection fraction [EF]), taken at baseline, peak dobutamine stress and in recovery for each DSE.

Secondary outcome measures

1. Tissue Doppler
2. Strain imaging
3. Strain rate

These outcome measures are taken at baseline, peak dobutamine stress and in recovery for each DSE.

Overall study start date

01/08/2008

Completion date

31/07/2009

Eligibility**Key inclusion criteria**

Subjects aged 35 - 80 years with coronary disease awaiting revascularisation with normal left ventricular (LV) function with insulin resistance.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

20

Key exclusion criteria

1. Atrial fibrillation
2. Pacemakers
3. Valvular heart disease
4. Renal failure

Date of first enrolment

01/08/2008

Date of final enrolment

31/07/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Cardiovascular Medicine

Cambridge

United Kingdom

CB2 0QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.addenbrookes.org.uk/>

ROR

<https://ror.org/04v54gj93>

Funder(s)

Funder type

Government

Funder Name

Internal funding

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	01/03/2010		Yes	No