

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

Contact name

Dr David Dutka

Contact details

Department of Cardiovascular Medicine
Box 110
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ
+44 (0)1223 331504
dpd24@medschl.cam.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

2008-000300-89

Protocol serial number

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-ischæmic 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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre
Department of Cardiovascular Medicine
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

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

Funder(s)

Funder type
Government

Funder Name
Internal funding

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	01/03/2010		Yes	No