ISRCTN78649100 https://doi.org/10.1186/ISRCTN78649100

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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/07/2008	**Overall study status** Completed	
Last Edited 18/01/2010	**Condition category** Circulatory System	

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

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
Research and Development Department
Box 277
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ
+44 (0)1223 274486
randdenquires@addenbrookes.nhs.uk

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