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

Submission date
19/03/2013

Recruitment status
No longer recruiting

Registration date
09/04/2013

Overall study status
Completed

Last Edited
16/03/2020

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cardiologists use tests such as dobutamine stress echocardiography to look at the effect of narrowings of the coronary arteries on heart muscle function. We know that factors other than the severity of the narrowings can alter individual responses during the test. Sitagliptin is a tablet used for the treatment of diabetes and we have previously shown that a single dose of the tablet can produce an improvement in heart muscle function during dobutamine stress echocardiography. We are now interested in finding out whether giving sitagliptin for a longer period can produce a long term benefit.

Who can participate?
We are inviting patients who have type 2 diabetes and have had angina or other evidence of narrowings in the coronary arteries.

What does the study involve?
Patients will be invited to attend for two visits. For both they will have fasted from the night before. On the first visit we will perform a standard stress echo during an intravenous infusion of a drug called dobutamine, which will steadily increase the heart rate, in a similar fashion to exercising. Patients will have their heart rate and blood pressure monitored throughout. This visit will take about 2 hours. We will then ask patients to take the study medication, sitagliptin, once daily for 4 weeks. After this 4 week period, patients will be asked to attend for the second visit when we will repeat the tests done on the first visit. This visit will also last about 2 hours. The first scan assesses the function of the heart under normal metabolic conditions. The second scan assess the heart under the altered metabolic conditions and the two are later compared and analysed.

What are the benefits and risks of participating?
The study drug, sitagliptin, is a fully licensed drug in use in the UK for the treatment of diabetes. It is therefore safe, and significant side effects are rare. These include nausea (<10%), somnolence (<1%), upper abdominal pain (<1%) and diarrhoea (<1%). Unlike several other diabetes medications, the risk of a low blood sugar after taking the tablet is very low. There are

no serious interactions with any other medications. We cannot promise that the study will help patients but the results will advance our understanding of coronary artery disease (narrowings) and diabetes, and direct the search for better treatments for it in the future.
We believe that the risks are small. The stress echo scan has been performed safely for many years using the same drugs and setup that we plan to use. During the scan patients may experience some angina (although not usually as much as on a treadmill test) or light-headedness. Some patients feel nauseated and sweaty. These are usually short lasting and stop once the drug is switched off. If necessary, the scan can be stopped at any time. In rare cases the heart rhythm becomes abnormal. This usually corrects itself. The risk of a serious complication is less than 1 in 500.

Where is the study run from?
The Clinical Research Facility at the Addenbrooke's Centre for Clinical Investigation in Cambridge (UK).

When is the study starting and how long is it expected to run for?
The study started in February 2011 and is to run for approximately 2 years.

Who is funding the study?
The study has been funded by the Medical Research Council (London, UK) and supported in part by the Investigator-Initiated Studies Program at Merck.

Who is the main contact?
Dr David Dutka
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2009-012776-27

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2.1

Study information

Scientific Title
The effect of sitagliptin on myocardial performance in patients with type 2 diabetes and coronary artery disease

Study objectives
In patients with type 2 diabetes 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 Essex Research Ethics Committee 1 on the 14 August 2009 (ref: 09/H0301/47)

Study design
Single centre interventional open trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

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 in patients with type 2 diabetes mellitus

Interventions
Subjects undergo two separate dobutamine stress echoes (DSE) (which last about half an hour); the first (control) while taking their usual oral hypoglycaemic agents, and the second after the

addition of 100mg od Sitagliptin (Januvia®) for approximately 4 weeks. A number of different DSE measurements are then compared between the two scans.

Intervention Type
Drug

Phase
Not Applicable

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
01/02/2011

Completion date
01/04/2013

Eligibility

Key inclusion criteria
Patients (male and female participants who are over the age of 18 years) with type 2 diabetes on metformin, sulphonylureas or thiazolidinediones and known to have coronary artery disease will be invited to participate in the study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Key exclusion criteria
1. Patients with resting LV dysfunction (ejection fraction <40% or regional wall motion abnormalities)
2. History of myocardial infarction within the preceding 3 months
3. Significant myocardial hypertrophy, valve disease or conduction abnormality
4. Pacemaker
5. Diabetes receiving insulin or exenatide therapy
6. Renal impairment (serum creatinine > 175 µmol/l)
7. Severe co-morbid illness
8. Women of childbearing potential

Date of first enrolment
01/02/2011

Date of final enrolment
01/04/2013

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
Addenbrooke's Hospital Box 277
Hills Road
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Sponsor type
Hospital/treatment centre

Website
http://www.addenbrookes.org.uk/

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Merck - supported in part by the Investigator-Initiated Studies Program

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	01/03/2014		Yes	No
HRA research summary			28/06/2023	No	No