Diastolic RV EvAluation with Millar catheter to investigate the effect of Glucagon-Like Peptide-1 (GLP-1) on right ventricular function during elective coronary angioplasty and stenting

Submission date	Recruitment status No longer recruiting	Prospectively registered		
22/10/2014		Protocol		
Registration date	Overall study status	Statistical analysis plan		
22/10/2014 Last Edited	Completed Condition category	Results		
		[] Individual participant data		
07/06/2019	Circulatory System	Record updated in last year		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT02236299

Secondary identifying numbers

17088

Study information

Scientific Title

Diastolic RV EvAluation with Millar catheter to investigate the effect of Glucagon-Like Peptide-1 (GLP-1) on right ventricular function during elective coronary angioplasty and stenting

Acronym

DREAM GLP-1

Study objectives

The heart requires nutrients and oxygen carried in the blood to generate energy for healthy pump function. Blood is supplied via heart vessels called coronary arteries. When the arteries narrow we call this coronary artery disease. Narrowing and blockage of the coronary arteries can cause chest pain (angina), breathlessness (due to a reduction in pump function) and if prolonged even irreversible muscle damage known as a heart attack. We can treat patients with coronary artery disease with drugs that reduce the workload on the heart or with balloons and hollow metal tubes (stents) to open the narrowed coronary arteries and improve the blood supply. These treatments can relieve angina, improve breathlessness and avert heart muscle damage during a heart attack. A potential new mechanistic effect is emerging by modulating the type of fuel used by the heart to generate energy more efficiently has been tested in the left ventricle. This study is designed to see if mechanistic effect provides the same protection in the right ventricle. It is hoped that this may further improve heart pump function and reduce the size of a heart attack in patients with coronary artery disease.

Ethics approval required

Old ethics approval format

Ethics approval(s)

East of England - Cambridge South Research Ethics Committee, 13/06/2014, ref: 14/EE/0141

Study design

Randomised; Interventional; Design type: Treatment

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Topic: Cardiovascular disease; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions

GLP-1, GLP-1

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Improvement in RV diastolic dysfunction

Secondary outcome measures

Not provided at time of registration

Overall study start date

22/09/2014

Completion date

22/03/2016

Eligibility

Key inclusion criteria

- 1. Age over 18
- 2. Able to give informed consent
- 3. Elective percutaneous intervention for a single vessel right coronary artery stenosis >75%
- 4. Normal right ventricular function

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 30; UK Sample Size: 30

Key exclusion criteria

- 1. Severe comorbidity expected life (<6months)
- 2. Nicorandil or a GLP1 receptor agonist or DPP4 inhibitor use

- 3. Women of child bearing age
- 4. Myocardial infarction within the previous 3 months
- 5. Previous coronary artery bypass graft to the RCA
- 6. Significant known left to right shunt
- 7. Permanent pacemaker
- 8. Atrial fibrillation

Date of first enrolment

22/09/2014

Date of final enrolment

22/03/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Papworth Everard

Cambridge United Kingdom CB3 8RE

Sponsor information

Organisation

Papworth Hospital NHS Trust (UK)

Sponsor details

Papworth Everard Cambridge England United Kingdom CB3 8RE

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/01qbebb31

Funder(s)

Funder type

Government

Funder Name

NIHR CSO Healthcare Science Fellowship; Grant Codes: NIHRHCSD120314

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?
HRA research summary			28/06/2023	No	No