ISRCTN03253693 https://doi.org/10.1186/ISRCTN03253693

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

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

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