ISRCTN49645414 https://doi.org/10.1186/ISRCTN49645414

Effect of Remote Ischaemic preConditioning on contrast medium induced nephropathy (CIN) (ERICCIN)

Submission date	Recruitment status	[X] Prospectively registered
28/06/2013	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/06/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/05/2018	Circulatory System	

Plain English summary of protocol

Background and study aims
The objective of this study is to investigate whether a new intervention called 'Remote Ischaemic PreConditioning' (RIPC) can reduce the incidence of contrast nephropathy, an acute kidney injury caused by the contrast medium (a substance used to enhance the contrast of structures or fluids within the body in medical imaging) that is used during coronary angiography and angioplasty. It is thought that the contrast medium damages the kidney by reducing kidney blood flow as well as by a direct toxic effect. It is known that an already existing kidney dysfunction is the main pre procedure risk factor for contrast induced kidney injury in addition to a number of other factors such as age over 75, diabetes, anaemia and heart failure. RIPC is a new concept which involves repeated inflation of a blood pressure cuff on the upper arm or leg to cause reduced blood flow and a local oxygen shortage (ischaemia) in the arm or leg tissue. It is thought that the 'ischaemic' tissues release pro survival proteins which also protect other organs in the body from reduced blood flow. Several studies have shown a protective effect in a number of situations including during heart attacks and heart surgery. To date, two small studies have suggested that RIPC can reduce the incidence of contrast nephropathy.

Who can participate?
Male and female patients between the age of 18 and 85, who are awaiting coronary angiography or angioplasty, are able to give informed consent and who have reduced kidney function. The study aims to recruit 360 patients.

What does the study involve?
Patients will be randomly allocated to receive either the 'remote ischaemic preconditioning' treatment or a placebo (dummy). Both groups will then undergo the planned coronary angiogram or angioplasty with the standard measures taken to reduce the risk of an acute kidney injury. Blood and urine tests will be collected prior to and after the procedure to assess whether the treatment has been effective in preventing damage to the patients' kidneys. Patients will be followed up at three months to assess whether there has been any persistent kidney injury or cardiovascular events.

What are the possible benefits and risks of participating?
The benefit of the study will be an increase in the scientific understanding of how RIPC may lead to a reduction in contrast medium induced nephropathy (CIN) and cardiovascular outcomes, as suggested by previous studies. RIPC is known to be a safe intervention with no documented significant adverse effects. Some patients have reported mild discomfort or minor skin bruising at the cuff site during cuff inflation which is temporary.

Where is the study run from?
1. Heart Hospital UCLH (UK)
2. Basildon & Thurrock University Hospital (UK)
3. East Surrey Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2013 to April 2017

Who is funding the study?
The study is being funded by The Hatter Cardiovascular Institute, UCL, as part of a BHF programme grant

Who is the main contact?
Prof. Derek Yellon
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14361

Study information

Scientific Title
A single-centre double-blinded randomised placebo-controlled study investigating the Effect of Remote Ischaemic preConditioning on Contrast medium Induced Nephropathy in at-risk patients undergoing coronary angiography or PCI (ERICCIN)

Acronym
ERICCIN

Study objectives
Remote Ischaemic Preconditioning reduces the incidence of contrast nephropathy in at-risk individuals undergoing coronary angiography or angioplasty.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Queen Square, 04/06/2013, ref: 13.LO.0502

Study design
Randomised interventional prevention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet: Ms Liz Owen, The Hatter Cardiovascular Institute, 67 Chenies Mews, London WC1E 6HX

Health condition(s) or problem(s) studied
Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
Suitable participants awaiting coronary angiography or angioplasty who have impaired kidney function will be stratified into high, medium and low risk groups and then randomly assigned in blocks to receive either the 'remote ischaemic preconditioning' treatment or a placebo.

Remote Ischaemic Conditioning, BP cuff inflation on the upper arm to 200mmHg for 5 minutes followed by deflation for 5 minutes. In total four cycles of inflation/deflation administered.

Follow Up Length: 3 months

Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Contrast Induced Nephropathy; Timepoint(s): Incidence of creatinine elevation by 25% or 0.5g/dl from baseline at 48 hours.

Secondary outcome measures
1. Cardiovascular endpoints; death, MI, revasc, acute heart failure, haemorrhage, rehospitalisation, haemodialysis at 3 months
2. Neutrophil gelatinase-associated lipocalin (NGAL); Timepoint(s): Serum NGAL elevation from baseline at 6 hours post contrast exposure
3. Persistent CIN; Timepoint(s): Incidence of creatinine elevation by 25% / 0.5g/dl from baseline at 3 months post contrast exposure
4. Proteinuria; Timepoint(s): Elevation of dipstick protein and ACR at 48 hours and 3 months following contrast exposure

Overall study start date
01/05/2013

Completion date
01/03/2017

Eligibility

Key inclusion criteria
1. Age 18 to 85
2. Male or female gender
3. Awaiting coronary angiography or percutaneous coronary intervention, or (added 09/01/2015) CRTD implantation
4. Renal dysfunction with eGFR (MDRD) <60 ml/min/1.73m2

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 362; UK Sample Size: 362; Description: Patients awaiting elective or emergency coronary angiography/PCI/CRTD with baseline eGFR (MDRD) <60 ml/min

Key exclusion criteria
1. Age under 18 or over 85
2. Inability to give written informed consent
3. Pregnancy
4. Haemo or peritoneal dialysis patients
5. Contraindication to BP cuff inflation such as significant upper limb peripheral vascular disease
6. Coagulopathy with INR >2.0
7. ST elevation MI/cardiac arrest/cardiogenic shock during admission
8. Participation in another clinical trial within 3 months
9. Intravascular Contrast Exposure within prior 1 month

Date of first enrolment
14/08/2013

Date of final enrolment
28/10/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Heart Hospital, University College London Hospitals
16-18 Westmoreland Street
London
United Kingdom
W1G 8PH

Study participating centre
Basildon & Thurrock University Hospital
Basildon
United Kingdom
SS16 5NL

Study participating centre
East Surrey Hospital
Canada Avenue
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RH1 5RH

Sponsor information

Organisation
University College London (UK)

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Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (BHF) (UK) Grant Codes: RG/08/015/26411

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name
University College London Hospitals NHS Foundation Trust

Alternative Name(s)
University College London Hospitals, UCLH

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trialists intend to publish the study findings in a high-impact peer reviewed journal shortly.

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository at The Hatter Cardiovascular Institute, UCLH. In accordance with its current Records Retention Schedule, research data is retained by UCL as sponsor for 20 years after the research has ended. The UCL Records Office provides a service to UCL staff and maintains records in a safe and secure offsite location and access to stored records is strictly controlled.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/03/2014		Yes	No
Basic results		14/05/2018	14/05/2018	No	No