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RIPCIN study: Remote Ischemic Preconditioning to reduce Contrast-Induced Nephropathy

Submission date
13/02/2013

Recruitment status
No longer recruiting

Registration date
27/02/2013

Overall study status
Completed

Last Edited
03/11/2015

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Contrast is a form of dye that improves the visibility of organs during diagnostic and treatment procedures. Contrast can also cause damage to the kidneys, called contrast-induced nephropathy (CIN), by interrupting the kidneys' blood flow. Remote Ischemic PreConditioning (RIPC) is a new treatment which involves repeatedly inflating a blood pressure cuff on the upper arm, causing reduced blood flow in the arm, which sends a signal that may protect the kidneys from reduced blood flow. The aim of this study is to evaluate the effect of RIPC in patients at a high risk of CIN.

Who can participate?
Patients aged over 18 who are undergoing diagnostic/treatment contrast procedures, and who are at a high risk of CIN.

What does the study involve?
Participants are randomly allocated to either the experimental group or the control group. In the experimental group patients undergo RIPC - four cycles of inflating and deflating a blood pressure cuff on the forearm. The control group receives the same procedure but the blood pressure cuff does not inflate to the necessary pressure (sham/dummy preconditioning). All participants provide blood and urine samples and complete a short questionnaire.

What are the possible benefits and risks of participating?
We expect that RIPC will be a non-invasive, simple, low-cost and safe method to reduce CIN in high-risk patients. RIPC is considered safe and as far as we know there are no complications.

Where is the study run from?
Radboud University Medical Center (Netherlands).

When is the study starting and how long is it expected to run for?
October 2012 to October 2013.

Who is funding the study?
Radboud University Medical Center (Netherlands) and Cook Medical.

Who is the main contact?
Dr Michiel Warle

Contact information

Type(s)
Scientific

Contact name
Dr Michiel Warle

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Remote Ischemic Preconditioning to reduce Contrast-Induced Nephropathy: a blinded randomized controlled trial

Acronym
RIPCIN

Study objectives
Remote ischemic preconditioning reduces contrast-induced nephropathy in high-risk patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee 'CMO Arnhem/Nijmegen' (Netherlands), 16/10/2012 , ABR Number: 41890, CMO File number: NL41890.091.12

Study design

Multi-center blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
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
Contrast-induced nephropathy

Interventions
The researcher performs the sham preconditioning or ischemic preconditioning procedure.

RIPC will be applied by 4 cycles of 5 minutes inflation and 5 minutes deflation of a standard blood pressure cuff around the upper arm at a pressure of the actual systolic blood pressure plus 50 mmHg.

Sham preconditioning will be applied in a similar fashion as the RIPC stimulus, but the blood pressure cuff is inflated to the actual diastolic blood pressure minus 10 mmHg.

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measures as of 14/04/2014:
Change in serum creatinine levels from baseline (day prior to contrast administration) to 48-72 hours after contrast administration

Previous primary outcome measures:
Change in serum creatinine levels from baseline (day prior to contrast administration) to 48 hours after contrast administration

Secondary outcome measures
Current secondary outcome measures as of 14/04/2014:
1. Change in biomarkers (for kidney injury) levels in blood and urine from baseline to 4-6 hours after contrast administration.
2. Incidence of CIN (>25% and/or 0.5 mg/dL rise in serum creatinine)
3. Death, rehospitalization and/or hemodialysis within 6 weeks after contrast-administration

Previous secondary outcome measures:
1. Change in biomarkers (for kidney injury) levels in blood and urine from baseline to 24 and/or 48 hours after contrast administration.
2. Incidence of CIN (>25% rise in serum creatinine)
3. Death, rehospitalization and/or hemodialysis within 6 weeks after contrast-administration

Overall study start date
01/10/2012

Completion date
01/10/2013

Eligibility

Key inclusion criteria
1. Interventions with expected intravascular contrast volume > 100 mL:
1.1. Thoracic Endovascular Aortic Repair (TEVAR)
1.2. Endovascular Aortic Repair (EVAR)
1.3. Digital Substraction Angiography (DSA)
1.4. Percutaneous Transluminal Angioplasty (PTA)
1.5. Percutaneous Intentional Endovascular Revascularisation (PIER)
1.6. Carotic Artery Stenting (CAS)
1.7. Percutaneous coiling/embolisation procedures
1.8. Computed Tomographic Angiography
2. High-risk of CIN (according CBO guideline):
2.1. eGFR <45ml/min
2.2. eGFR <60ml/min and diabetes
2.3. eGFR <60ml/min ans 2 additional risk factors [peripheral artery disease, heart failure, >75 years, anaemia (Ht<0,39 for men and <0,36 for women), dehydration, use of diuretics and/or NSAID].
3. Informed consent
4. Both male and female, age > 18 years (no upper limit)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
76

Key exclusion criteria

1. Age < 18 years
2. Hemo- and peritoneal dialysis
3. Concomitant inclusion in another interventional study
4. Percutaneous coiling/embolisation procedures of the kidney

Date of first enrolment
01/10/2012

Date of final enrolment
01/10/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
Geert Grooteplein zuid 10
Nijmegen
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6525 GA

Sponsor information

Organisation
Radboud University Nijmegen Medical Centre (Netherlands)

Sponsor details
Geert Grooteplein zuid 10
Department of Surgery, route 690
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6525 GA

Sponsor type
Hospital/treatment centre

Website
http://www.ru.nl/

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
University/education

Funder Name
Radboud University Nijmegen Medical Centre (Netherlands)

Funder Name
Cook Medical

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?
Protocol article	protocol	11/04/2014		Yes	No
Results article	results	01/10/2015		Yes	No