

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

Submission date 13/02/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/02/2013	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 03/11/2015	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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 Subtraction Angiography (DSA)
 - 1.4. Percutaneous Transluminal Angioplasty (PTA)

- 1.5. Percutaneous Intentional Endovascular Revascularisation (PIER)
- 1.6. Carotid 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 and 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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Sponsor information

Organisation

Radboud University Nijmegen Medical Centre (Netherlands)

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

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