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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
Geert Grooteplein zuid 10
Department of Surgery, route 690
Nijmegen
Netherlands
6525 GA

# 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 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

### 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

**Geert Grooteplein zuid 10**
Nijmegen
Netherlands
6525 GA

# 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |