

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

<b>Submission date</b> 13/02/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/02/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/11/2015	<b>Condition category</b> Urological and Genital Diseases	<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**  
Geert Grooteplein zuid 10  
Department of Surgery, route 690  
Nijmegen  
Netherlands  
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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 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

**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

Netherlands

6525 GA

## Sponsor information

**Organisation**

Radboud University Nijmegen Medical Centre (Netherlands)

**Sponsor details**

Geert Grooteplein zuid 10

Department of Surgery, route 690

Nijmegen

Netherlands

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?
<a href="#">Protocol article</a>	protocol	11/04/2014		Yes	No
<a href="#">Results article</a>	results	01/10/2015		Yes	No