Helios Study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29385

Source
NTR

Brief title
Helios Study

Health condition

- contrast induced nephropathy
- acute kidney injury
- contrastnefropathie
- acute nierinfufficiëntie

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: self-financing research, non-sponsored trial

Intervention

Outcome measures

Primary outcome

Mean increase in serum creatinine 2-4 days after contrast administration.

Secondary outcome

1. Contrast induced nephropathy defined as an increase in serum creatinine > 25% or 44 umol/liter 2-4 days after contrast administration;

2. Chronic loss of renal function after 2 months defined by the definition of contrast induced nephropathy;

3. Contrast induced need for dialysis;

4. Heartfailure due to volume suppletion with an indication for diuretics;

5. Chronic loss of renal function 1 year after contrast administration definined as an increase in serum creatinine > 25% of > 44 µmol/l,

Study description

Background summary

N/A

Study objective

A brief sodium bicarbonate infusion of 250 ml 1 our prior to contrast administration is non-inferior to pre and posthydration with a 1000 ml sodium chloride for and after the procedure.

Study design

1. Before contrast adminisatrion;

2. 2-4 days after contrast administration;

3. 2 months after contrast administration;

4. 1 year after contrast administration.

Intervention

1. 250 mL Sodium Bicarbonate 1 hour prior to contrast administration vs.

2. 1000 ml Sodium Chloride prior and after contrast administration.

Contacts

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Eligibility criteria

Inclusion criteria

1. eGFR < 60ml/min/1.73m2;

2. In and outpatients.

Exclusion criteria

1. Age < 18 years;

2. Patients with a known allergy for contrast media;

3. Pregnancy;

4. Previous contrast adminisatrions in the last 7 days;

5. No informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-01-2011
Enrollment:	300
Type:	Actual

Ethics review

Positive opinion

Date:	17-01-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37953
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2574

Register	ID
NTR-old	NTR2699
CCMO	NL33992.058.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37953

Study results

Summary results

N/A