Sodium Bicarbonate versus Saline for the prevention of Contrast Induced Nephropathy in patients undergoing computed tomography.

No registrations found.

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

Summary

ID

NL-OMON21374

Source
Nationaal Trial Register

Brief title
The Salina Study

Health condition

Prevention, Contrast Induced Nephropathy, Computed Tomography, hydration

preventie, contrastnefropathie, CT-scan, hydratie

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: Leiden University Medical Center (LUMC)

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/L 2-4 days after contrast administration;

2. Chronic renal impairment defined as an increase in serum creatinine > 25% or > 44 umol/L 2 months after contrast administration;

3. Development of an indication for renal replacement therapy.

Study description

Background summary

N/A

Study objective

H0= Saline is inferior to sodium bicarbonate for the prevention of contrast induced nephropathy in patients undergoing computed tomography after intravenous contrast administration.

H1= Saline is noninferior to sodium bicarbonate for the prevention of contrast induced nephropathy in patients undergoing computed tomography after intravenous contrast administration.

Study design

1. 4 hours after computed tomography;

2. 3 (+/- 1 day) after computed tomography;

3. 2 months after computed tomography when contrast induced nephropathy is diagnosed after 3 days (2).

Intervention

Group 1: Sodium Bicarbonate 1.4% 1 hour prior to computed tomography 250 mL. No posthydration.

Group 2: Sodium Chloride 0.9% 1 ml/hr/kg bodyweight, during 12 hours for and after

computed tomography.

Contacts

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Eligibility criteria

Inclusion criteria

1. eGFR < 45 ml/min/1.73m2;

2. eGFR < 60 ml/min/1.73m2 and diabetes mellitus.

Exclusion criteria

1. Age < 18 years;

2. Exposure to radiographic contrast media within 7 days;

3. Pregnancy;

4. Allergy for low osmolar contrast media.

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):	07-02-2010
Enrollment:	574
Type:	Actual

Ethics review

Positive opinion

Date:	23-12-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38407
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2032
NTR-old	NTR2149
CCMO	NL27494.058.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38407

Study results

Summary results
N/A