Sodium Bicarbonate for the prevention of contrast induced nephropathy in patients suspected with acute pulmonary embolism undergoing CTPA.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25804

Source
Nationaal Trial Register

Brief title
The Nefros Study

Health condition

Contrast Induced Nephropathy (contrastnefropathie)
CT-pulmonary angiography (CTPA)
Sodium bicarbonate (natriumbicarbonaat)
Prevention (preventie)

Sponsors and support

Primary sponsor: Name: Judith Kooiman
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Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Mean increase in serumcreatinine 2-4 days after CT-PA.

Secondary outcome

1. Increase in serum creatinine > 25% or > 44 umol/l, 3 days (+/- 1 day) after CT-PA with contrast media;

2. Increase in serum creatinine >25% or > 44 umol/l 2 months after CTPA with contrast media or the need for dialysis;

3. Increase in C-cystatine and NGAL 3 days (+/- 1 day) after CT-PA;

4. Increase in NGAL 2 hours after CT-PA.

Study description

Background summary

Contrast Induced Nephropathy (CIN) is a decrease in renal function following administration of radiographic contrast agents (defined as an increase in serum creatinine > 25% of > 44 umol). Patients with chronic renal impairment and diabetes are at high risk for CIN. To prevent CIN high risk patients receive hydration prior and post to contrast administration. However, when a patient is suspected of an acute pulmonary embolism (PE) there is no time for a hydration protocol with saline 12 hours prior to CTPA. Since the dosage of contrastmedia nessecary for CTPA is low and the contrastmedia are administered intravenously, the risk for CIN is low and hydration might not be nessecary.
Sodium bicarbonate has proven to be effective in preventing CIN when it is giving 1 hour prior and 6 hours after contrast administration.

The aim of our study is to analyse the mean increase in serum creatinine and the incidence of CIN following CTPA without prehydration compaired to a short prehydration regime with sodium bicarbonate during one hour. Furthermore, the risk of developing CIN after CT-PA with iso-osmolair contrast media is studied for both groups.

Study objective

1. H0= Placebo is inferior to sodium bicarbonate in the prevention of contrast induced

nephropathy in patients undergoing CTPA;

2. H1=Placebo is noninferior to sodium bicarbonate in the prevention of contrast induced nephropathy in patients undergoing CTPA.

Study design

1. 2 hours after CTPA;

2. 3 days (+/- 1 day) after CTPA;

3. 2 months after to CTPA when contrast induced nephropathy has been diagnosed.

Intervention

1. Sodium Bicarbonate 1 hour prior to CTPA 1 ml/kg bodyweight;

2. CTPA without any hydration.

Contacts

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Eligibility criteria

Inclusion criteria

Clinical suspected PE with an indication for CT-PA with intravenous administration of iso-

osmolair contrast media and eGFR < 60 ml/min.

Exclusion criteria

1. Age < 18 years;

2. Exposure to contrast media within 7 days;

3. Pregnancy;

4. Allergy to contrastmedia;

5. Systolic bloodpressure < 100 mmHg.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-07-2009
Enrollment:	264
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-08-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1847
NTR-old	NTR1958
Other	2009-013547-11 : EudraCTnumber
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A