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

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- Evaluation of mean increase in serum creatinine and the incidence of CIN following CT-PA without prehydration compaired to a short prehydration regime with sodium bicarbonate during one hour.- Furthermore, the risk of developing CIN after CT-PA...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Interventional

Summary

ID

NL-OMON38375

Source
ToetsingOnline

Brief title
The Nefros study

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Nephropathies

Synonym
acute renale failure following contrast, contrastnephropathy

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Contrast Induced Nephropathy, CTPA, prevention, sodium bicarbonate

Outcome measures

Primary outcome

* mean increase in serumcreatinine 2-4 days after CT-PA.

Secondary outcome

* Increase in serum creatinine > 25% or > 44 µmol/l 4 days (+ / - 1 day) after

CTPA with contrast media.

* Increase in serum creatinine > 25% or > 44 µmol/l 2 months after CTPA with

contrast media or the need for dialysis.

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

* Increase in NGAL 2 hours after CT-PA.

Study description

Background summary

Contrast induced nephropathy (CIN) can occur after injecting radiographic iso osmolair contrast media. Patients with renal impairment or a decreased renal function in combination with diabetis mellitus or Kalher's disease are at risk for developing CIN.
A consensus of the CBO (Dutch Central guidance institute) advises to give patients at risk a pre- and posthydration treatment each during 12 hours with 0,9% saline 1 ml/hr/kg bodyweight. In case of emergencies (non elective examinations) a short pre-hydration during one hour with sodium bicarbonaat 1.4% 3 ml/hr/kg bodyweight is indicated, followed by a posthydration of 6 hours 1.4% sodium bicarbonate 1.5 ml/hr/kg bodyweight. This hydration regime is studied in patient populations undergoing coronairy angiography. There is no

consensus on the exact implementation of hydration regimes with sodium bicarbonate.

It is important to underline the vital indication of CTPA.

The risk of CIN is not only dependent of the risk profile of the patient but also of the nature of examination, the amount of injected contrast media, the distinction between, low, iso, en high osmolair contrast media and wheter contrast media is injected intravenous or in the arterial circulation.

CIN has a low incidence following CTPA because of the low amounts of contrast media, which is injected intravenous in a iso-osmolair concentration. Furthermore, very few patients who develop CIN are not able to restore kidney function after two months.

It is important to find out wheter prehydration prior to CTPA with a low contrast load has a preventive effect on CIN because of the direct implication it has on the safety and the amount of stress on the patient.

Study objective

- Evaluation of mean increase in serum creatinine and the incidence of CIN following CT-PA 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 patient groups.

Study design

Patients with an indication for hydration, are asked to participate in this study. Patients a randomly asigned to one of the study arms.

- Group 1: sodium bicarbonate 1,4% (3ml/kg bodyweight) 1 hour prior to administration of contrast media.
- Group 2: CT-PA without any hydration

Markers for kidney function and kidney damage are measured prior, 2 hours, 2-4 days and 2 months after CTPA. These measurement are used to determine the mean increase in serum creatinie, the incidence of CIN and the confidence interval of the incidence of CIN and the risk for developing CIN in both groups.

Intervention

* group 1: sodium bicarbonaat 1,4% (3 ml/kg bodyweight) 1 hour prior to administration of contrast media.

* group 2: CT-PA without any hydration.

Study burden and risks

The amount of stress on the patient for this study is very limited. Renal function is rountinely measured prior to CT-PA. In this study, patients will receive one extra venapuncture prior and two hours after CT-PA and are asked for one portion of urine prior and after CT-PA.
The CBO advises to check renal function 2-4 days after CT-PA of all patients at risk for CIN. In this study we will ask for one extra venapuncture and one urine portion after 2 to 4 days.
If the renal function is decreased after 2 to 4 days according to the defenition of CIN, patients are asked to come back after 2 months for some extra bloodwork to determine whether there kidney function is restored or not. This is not clinical practice.
Participation in this study results in one extra hospital visit if CIN is established after 2 to 4 days. Patients probably will have advantage of this accurate monitoring of kidney function.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

eGFR < 60 ml/min

Exclusion criteria

* age < 18 years
* exposure to radiographic contrast media within 7 days
* pregnancy
* systolic bloodpressure < 100 mmHg
* allergy for iso osmolar contrast agents

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-11-2009
Enrollment:	140
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Sodium Bicarbonaat infusion
Generic name:	Sodium Bicarbonaat infusion
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	13-07-2009
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	16-07-2009
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	09-06-2010
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	15-03-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
EudraCT	EUCTR2009-013547-11-NL
CCMO	NL27202.098.09