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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25804

Bron
Nationaal Trial Register

Verkorte titel
The Nefros Study

Aandoening

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

Ondersteuning

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Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

2. CTPA without any hydration.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Clinical suspected PE with an indication for CT-PA with intravenous administration of iso-osmolair contrast media and eGFR < 60 ml/min.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age < 18 years;

2. Exposure to contrast media within 7 days;

3. Pregnancy;

4. Allergy to contrastmedia;

5. Systolic bloodpressure < 100 mmHg.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	09-07-2009
Aantal proefpersonen:	264
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-08-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A