CINCOR* Trial III:Clinical Study of the CINCOR Contrast Removal Study for Patients with Chronic Kidney Disesease

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The purpose of this clinical study is to provide confirmation of the clinical safety and performance of the CINCOR* System in removing contrast in patients at risk of developing CIN who are undergoing percutaneous coronary procedures.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON38061

Source
ToetsingOnline

Brief title
CINCOR* Trial III

Condition

- Coronary artery disorders
- Nephropathies

Synonym
chronic kidney disease

Research involving
Human

Sponsors and support

Primary sponsor: Osprey Medical
Source(s) of monetary or material Support: osprey medical

Intervention

Keyword: chronic kidney disease (CKD), CINCOR, contrast, percutaneous coronary intervention (PCI)

Outcome measures

Primary outcome

Safety:

To describe the safety of the CINCOR* System by analyzing all system related adverse events and calculating the serious system related event-free rate at 30 days post-procedure.

Performance:

Rate of successful coronary sinus cannulation

Time required for coronary sinus cannulation

Volume of contrast agent used to place the Removal Catheter

Diameter of the coronary sinus based on fluoroscopy images

Total fluoroscopy time

Total volume of blood collected during removal episodes

Secondary outcome

* To estimate the rate of CIN in treated patients compared to historical controls.

* To summarize the change in serum creatinine and estimated glomerular filtration (eGFR) pre-procedure to 1 day and 4 days post-procedure.

* Evaluate the percent of contrast media removal

* To describe the safety of the CINCOR* System by summarizing all system

related adverse events and estimating the serious system related event-free

rate through 30 days post-procedure.

* To estimate the rate of all Adverse Events (AE).

* To estimate the rate of the following AEs:

o Blood loss/bleeding meeting one of the following conditions:

- Requires transfusion of * 2 units

- Thrombolysis in Myocardial Infarction (TIMI) Major bleeding

- TIMI for Minor bleeding

Study description

Background summary

Retrospective studies of PCI databases indicate that chronic kidney disease patients undergoing PCI procedures have increased in-hospital and long-term morbidity and mortality.

Study objective

The purpose of this clinical study is to provide confirmation of the clinical safety and performance of the CINCOR* System in removing contrast in patients at risk of developing CIN who are undergoing percutaneous coronary procedures.

Study design

This is a prospective, single arm clinical trial. All enrolled patients will be followed through 30 days post-procedure.

Intervention

Placing contrast medium removal system CINCOR* in sinus coronarius during PCI

Study burden and risks

nature and extent of burden consists of additional visits (3x) either to the hospital or visits or b telephone. Extra venous puncture (3 times)
Prolongation of the procedure by 10 minutes. Extra Fluoroscopy
Risks dissection, sinus coronarius perforation, dissection of occlusion. Pulmonary embolism. Rythm disorders.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. The subject is a candidate for a therapeutic coronary PCI procedure of the left coronary artery (left main, left anterior descending coronary artery and/or left circumflex artery or

branches of these vessels).
2. The subject has documented CKD and an estimated eGFR > 20 and * 40 mL/min/1.73 m2 (as determined by the MDRD equation) ; or
an eGFR> 40 and < 60 mL/min/1.73 m2 and one or more of the following co-morbidities: stage III/IV congestive heart failure (as defined by NYHA criteria), diabetes mellitus, or 75 years of age or greater.

Exclusion criteria

1. The subject is currently undergoing renal dialysis.
2. The subject is in acute renal failure or has unstable renal function based on clinical findings and/or a known change in serum creatinine of * 0.5mg/dL or * 25% within 7 days prior to enrollment compared to the last serum creatinine measurement on record
3. The subject has received contrast media within 7 days prior to the procedure day or a second imaging study of any type which will require iodinated contrast is planned within the 30 days following the protocol-defined procedure

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-04-2012
Enrollment:	8
Type:	Actual

Medical products/devices used

Generic name:	CINCOR systeem
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	05-04-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL36962.018.11