# CINCOR* Trial

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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 patients at risk of developing CIN who are undergoing interventional percutaneous coronary procedures.Further, the data...

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|---|---|
| **Ethical review** | Not approved |
| **Status** | Will not start |
| **Health condition type** | Coronary artery disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON34043

**Source**
ToetsingOnline

**Brief title**
CINCOR* Trial

### Condition

- Coronary artery disorders
- Nephropathies

**Synonym**
Contrast-induced nephropathy, disease of the kidneys

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Osprey Medical Inc.
**Source(s) of monetary or material Support:** Osprey Medical Inc.

### Intervention

**Keyword:** Catheter-system, Contrast-Induced Nephropathy, Interventional percutaneous

coronary procedures

## Outcome measures

### Primary outcome

Safety :

* To describe the safety of the CINCOR* System by analysing 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 as a sub-study in selected centers

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:

Blood loss/bleeding meeting one of the following conditions:

Requires transfusion of * 2 units

Meets the definition for Thrombolysis in Myocardial Infarction (TIMI) Major or

Minor Bleeding

Coronary sinus perforation, dissection, or occlusion that requires treatment or

results in MI or death

Pericardial effusions (including pericardial tamponade) requiring treatment

Death

Myocardial infarction

Arrhythmias

Other events related to partial coronary sinus occlusion and suction

# Study description

**Background summary**

Chronic kidney disease (CKD) is a growing health concern in the United States and other western nations. The use of iodinated contrast agents has been strongly associated with the acute reduction in kidney function, a condition known as contrast-induced nephropathy (CIN).
Several strategies for preventing CIN have been evaluated. The basic strategies include: (1) choice and quantity of CM; (2) peri-procedural hydration; (3) end-organ protection; and (4) device based therapy. few effective prophylactic or therapeutic interventions have conclusively demonstrated evidence for reduction of CIN*. In fact, many patients at risk for CIN may not undergo diagnostic procedures because the risks outweigh the treatment benefits.
The advantage of the Osprey Medical CINCOR* System investigational device is in

achieving contrast retrieval sooner, prior to reaching the systemic circulation and the kidneys thereby helping to avoid the development of CIN.

## Study objective

The purpose of this clinical study is to provide confirmation of the clinical safety and performance of the CINCOR* System in patients at risk of developing CIN who are undergoing interventional percutaneous coronary procedures. Further, the data from this trial will be used to develop hypotheses for a randomized controlled trial to assess the effectiveness of the CINCOR* System in preventing CIN in indicated patients.

## Study design

The CINCOR* Trial will be conducted at up to 12 investigational centers in Europe, Australia, and New Zealand. Up to 100 subjects will be enrolled. The estimated time to complete enrollment is 12 months.

## Intervention

A specially designed balloon catheter is percutaneously inserted into the jugular or femoral vein and positioning inside the coronary sinus to remove contrast media from the cardiac circulation in patients undergoing coronary angiography procedures.
When X-ray dye is injected, the CINCOR* System will be activated for 8-12 seconds to collect a small amount of blood (about 1-1.5 tablespoons or 20-30mL) that contains the x-ray dye. This will be repeated for each x-ray picture. It is anticipated that no more that 500mL of blood will be collected in this way.

## Study burden and risks

It is anticipated that subjects participating in the study will be exposed to procedure and post-procedure risks similar to other interventional percutaneous coronary procedures involving subjects with normal or impaired renal function.

Possible risks associated with the investigational device may include but are not limited to:
* Allergic reaction to investigational device (nickel, titanium)
* Anemia
* Aneurysm, pseudoaneurysm, arteriovenous fistula
* Bleeding / re-bleeding
* Cardiac damage / perforation / tamponade
* Coronary Sinus Damage (perforation or rupture)
* Death
* Device failure
* Ecchymosis

* Embolism
* Fainting
* Fever, elevated temperature
* Heart rhythm disturbance
* Hematoma
* Hemorrhage
* Infection
* Myocardial infarction
* Open-heart surgery
* Pain
* Pulmonary embolism
* Renal failure requiring dialysis
* Stroke
* Transfusion
* Vessel trauma including a tear, unresolved dissection (separation of tissue layers), or perforation (hole)

Participation in this trial will involve exposure to an additional small amount of radiation above and beyond normal clinical management. This arises from the X-rays used to aid in the placement of the special catheter in the heart. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisievert (mSv) each year. The additional effective dose the patient will receive from entering this trial is approximately 0.3 mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure.

Every effort will be made to minimize these risks and any discomfort.

Patients that are pregnant or currently breast feeding, may not participate in this study.

The Osprey Medical CINCOR* System was subjected to a rigorous risk analysis as part of the design process. Based on the risk analysis, complete in vitro and in vivo testing was performed to demonstrate safety. The testing conducted on the Osprey Medical Contrast Removal System was designed to comply with the requirements of United States Food and Drug Administration (FDA) and EN ISO 14155 as well as other recognized national standards. The preclinical studies have demonstrated that the potential risks have been addressed as far as possible and that the device is as safe as feasibly possible prior to use in humans as part of this clinical study.
The investigational plan is specifically designed to minimize risks through careful subject selection, thorough training of investigator and adherence to the schedule of post-operative follow-up subject visits and regular clinical monitoring visits by designated monitoring personnel.

# 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 at least 21 years of age.
2. 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) anticipated to utilize at least 50 mL of iodinated contrast media (on the basis of a prior angiogram or pending angiographic confirmation).
3. 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.
4. The subject (or subject*s legal representative) is willing and able to provide appropriate informed consent.

5. The subject is willing and able to comply with the requirements of the study protocol, including the predefined follow-up evaluations.

## 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. If the serum creatinine has risen to this degree, then at least 2 serum creatinine measures drawn >48 hours but <7 days all within 0.5mg/dL must be present for a new baseline to be established.
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.
4. The subject is expected to undergo any of the following: ventriculography, aortography, renal angiography, or any other injection of >10 cc of contrast in total other than coronary angiography or PCI as described below.
5. The subject has a known allergy to iodine-based contrast agents that cannot be adequately pre-medicated (patients with a history of true anaphylaxis may not be enrolled).
6. The subject requires one or more of the following nephrotoxic agents: Aminoglycoside antibiotics, Sulfonamides, Amphotericin B, Levofloxacin, Ciprofloxacin, Rifampin, Tetracycline, Intravenous Acyclovir, Pentamidine, Penicillin and Cephalosporins, Cisplatin, Methotrexate, Mitomycin, Cyclosporine, Tacrolimus.
7. The subject has a known bleeding diathesis (e.g. thrombocytopenia [<100,000 cells/mm3], heparin-induced thrombocytopenia, hemophilia, or von Willebrand disease, any history of intracranial bleeding, or gastrointestinal bleeding gross genitourinary bleeding).
8. The subject is currently on intravenous heparin that cannot be discontinued at least 4 hours before the procedure, intravenous bivalirudin that cannot be discontinued at least 4 hours before the procedure, intravenous abciximab that cannot be discontinued at least 24 hours before the procedure, intravenous tirofiban or eptifibatide that cannot be discontinued at least 6 hours before the procedure, or has received any low molecular weight heparin within 12 hours or factor Xa antagonist (including fondaparinux) within 24 hours.
9. The subject has a known hypersensitivity to both heparin and bivalirudin or aspirin or all thienopyridine agents or iodinated contrast that cannot be adequately pre-medicated.
10. The subject is hypotensive (systolic blood pressure < 90 mmHg not corrected by intravenous saline) or requiring intravenous pressors and/or intra-aortic balloon counterpulsation.
11. The subject has decompensated heart failure requiring intravenous diuretic, inotropic, vasopressor or intraaortic balloon support in the previous 7 days.
12. The subject has had recent (within last 72 hours) acute myocardial infarction as defined in the *Universal Definition of Myocardial Infarction*:
a. Detection of rise and/or fall of cardiac biomarkers (preferably troponin) with at least one value above the 99th percentile of the upper reference limit and at least one of the following
i. Symptoms of ischemia
ii. ECG changes indicative of new ischemia (new ST-T changes or new left bundle branch

block)
iii. Development of pathological Q waves in the ECG
iv. Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality
13. The subject has undergone previous procedures involving both internal jugular vein(s) within last 8 weeks.
14. The subject requires an intra aortic balloon pump.
15. The subject has an International Normalized Ratio (INR) > 1.6 pre-procedure.
16. The subject has an active infection within the last month.
17. The subject has hemoglobin (Hb) < 10.0 g/dL within one (1) week of the procedure.
18. The subject is known to be or suspected to be pregnant, or is lactating (all women of child-bearing potential must have a negative pregnancy test within 72 hours before participating in this protocol).
19. The subject has a life expectancy of less than twelve (12) months.
20. The subject has a pacemaker lead, percutaneous mitral annuloplasty or other device placed within the coronary sinus.
21. The subject has an unstable clinical situation precluding placement or operation of the Osprey Medical CINCOR* System.
22. The subject is currently participating in another investigational device or drug study that has not completed its primary endpoint.

# Study design

## Design

**Study type:** Interventional

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 25 |
| Type: | Anticipated |

## Medical products/devices used

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|---|---|
| Generic name: | CINCOR System |
| Registration: | No |

# Ethics review

Not approved

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|---|---|
| Date: | 19-11-2010 |
| Application type: | First submission |
| Review commission: | TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam) |

# 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 | NL33663.101.10 |