# A Prospective, Multi-Center, Single Arm Study of the Conor Cobalt Chromium Reservoir Based Stent (Nevo) with Sirolimus Elution in Native Coronary Artery Lesions (CP-07 protocol)

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| **Ethical review** | Approved WMO |
| **Status** | Will not start |
| **Health condition type** | Coronary artery disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON32462

**Source**
ToetsingOnline

**Brief title**
Conor RES-ELUTION II NR study

### Condition

- Coronary artery disorders
- Cardiac therapeutic procedures

**Synonym**
coronary disease; atherosclerosis

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Conor Medsystems, LLC (maakt deel uit van Johnson & Johnson); contact persoon Emily Hergenreter
**Source(s) of monetary or material Support:** farmaceutische industrie

## Intervention

**Keyword:** drug-eluting stent, Percutaneous coronary intervention (PCI), Sirolimus

## Outcome measures

### Primary outcome

The primary endpoint of the study is target lesion failure (TLF) defined as a composite of clinically-driven target lesion revascularization, target vessel related myocardial infarction, or cardiac death that could not be clearly attributed to a vessel other than the target vessel at 12-months post-procedure.

### Secondary outcome

•Procedural endpoints: Lesion success, Device success, Procedure success.

•Clinical endpoints through 18 months post procedure and annually from 2 to 5 years post procedure: Target lesion revascularization (TLR) (total and clinically driven), Target vessel revascularization (TVR) (total and clinically driven), Target vessel failure (TVF) and its individual components, Major adverse cardiac events (MACE) (death, Q wave or WHO-defined non-Q wave myocardial infarction, emergent bypass surgery, or repeat target lesion revascularization) and its individual components.

•Safety endpoints through 18 months post procedure and annually from 2 to 5

years post procedure: Stent thrombosis (acute, sub-acute, late, very late), Bleeding events, Death (cardiac and non-cardiac), Myocardial Infarction (Q wave or WHO-defined non-Q wave), Stroke (hemorrhagic and non- hemorrhagic).

•Patient reported outcomes as measured by a quality of life (QOL) survey at baseline, 30 days, 6 months, 12 months, 18 months, and from 2-5 years post procedure.

# Study description

**Background summary**

Restenosis remains a frequent cause of late failure after initially successful coronary angioplasty occurring in as many as 20-40% of procedures performed. Restenosis following stenting is primarily a result of neointimal hyperplasia.

An increasing body of evidence has emerged demonstrating that local delivery of pharmacologic agents that inhibit cellular proliferation, and therefore neointimal hyperplasia, may lead to improved outcomes following coronary stenting. The advantages of local drug delivery include sufficient drug concentration in the treated segment while limiting systemic exposure and potential side effects.

The first agents to be studies for the prevention of coronary restenosis on a drug-eluting stent platform were sirolimus and paclitaxel. Sirolimus has an anti-proliferatieve action in T cells and smooth muscle cells and prevents proliferation and migration of smooth muscle cells in several models of restenosis and vascular disease.

**Study objective**

The primary objective of this study is to evaluate the target lesion failure rate of the Conor Sirolimus-eluting Coronary Stent System in lesions up to 28 mm in length in native coronary arteries with a reference vessel diameter of 2.5 mm to 3.5 mm compared to an OPC derived from historical data.

**Study design**

The RES-Elution II NR study is a prospective, multi-center, single-arm, open-label study for the treatment of
lesions in native coronary arteries. Clinical follow-up will take place at 30 days, 6 months, 12 months, 18 months
and annually from 2 through 5 years post-procedure.

**Intervention**

Standard procedure of balloon angioplasty with stenting procedure and con-comitant anti-platelets treatment.

**Study burden and risks**

The following risks relating to standard PTCA, stenting, and angiography may occur (listed in order of severity): Death; intima dissection (additional stent placing or surgical revascularisation), injury to the artery requiring emergency coronary artery bypass graft; Myocardial ischemia and/or infarction; Stroke/transient ischemic attack; Cardiac tamponade, Dissection, perforation, or rupture of the coronary artery; Embolism; Stent thrombosis/occlusion (early or late); Total occlusion of the artery; Restenosis of the stented artery; Coronary perforation; Aneurysm, pseudoaneurysm, or arteriovenous fistula; Arrhythmias including tachyarrhythmias, bradyarrhythmias or cardiac arrest; Hemorrhage, possibly requiring transfusion, as a result of the procedure or associated medications; Renal insufficiency or renal failure; Respiratory failure; Shock/pulmonary edema; Abrupt vessel closure or spasm; Hypotension/hypertension; Allergic reaction or hypersensitivity (to contrast, antiplatelet therapy, stent materials including metal, drug or polymers); Peripheral ischemia/peripheral nerve injury; Infection or fever; Unstable angina; atypical angina; chest pain; Pain/reaction at catheter insertion site; balloon rupture; Stent migration; Failure to deliver the stent to the intended site of treatment; Stent misplacement; Incomplete stent apposition; Stent compression; Stent fracture; Vasospasm; Hematoma. Deformed stents that cannot be implanted could also lead to problems associated with stent retrieval which could in turn expose the patient to longer procedure times and increased x-ray exposure.

Potential adverse events not outlined above but listed in the CYPHER® SELECT Plus and/or CYPHER® product labeling (Cordis Corporation) P020026 that may be related to sirolimus or to the sirolimus drug coating include: Immune suppression, especially in patients with hepatic insufficiency or who are taking medications that inhibit CYP3A4 or P-glycoprotein; Hypersensitivity, to the drug (sirolimus or its excipients) or to the polymer (or individual components) including anaphylactic/anaphylactoid type reactions; Changes in lipid metabolism which may include hypertriglyceridemia or hypercholesterolemia; Abnormal liver function tests; Anemia, low white blood cell count, or low platelet count; Joint pain/discomfort; Diarrhea; Increased

cholesterol or increased triglycerides; Low blood potassium levels; Infections; Interstitial lung disease; Lymphoma and other malignancies.

The bruden for the patient exists of ballon angioplasty with stenting procedure and anticoagulant therapy.
The patient will be admitted to the hospital for the ballon angioplasty with stenting procedure for 1-2 days.
Clinical follow-up will take place at 30 days, 6 months, 12 months, 18 months and annually from 2 through 5 years post-procedure. During this visits patient will be asked to complete a QoL questionnaire, ECG will be taken and the investigator will assess the patient's angina status. After 6 months an identical telephone visit will be done without the ECG.

## Contacts

**Public**
Conor Medsystems, LLC (maakt deel uit van Johnson & Johnson); contact persoon Emily Hergenreter

1003 Hamilton Court
Menlo Park, CA 94025
United States of America
**Scientific**
Conor Medsystems, LLC (maakt deel uit van Johnson & Johnson); contact persoon Emily Hergenreter

1003 Hamilton Court
Menlo Park, CA 94025
United States of America

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

Inclusion Criteria:;-1 Subjects with atherosclerotic CAD ;
-2 The subject must be >/= 18 years of age;
-3 Diagnosis of angina pectoris as defined by stable angina pectoris Canadian Cardiovascular Society Classification (Class I, II, III) OR non-ST segment elevation acute coronary syndrome (Braunwald Classification B&C) OR OR non-ST segment elevation myocardial infarction >= 48 hours from the time of study index procedure OR asymptomatic subjects with a positive stress test;
-4 Indicated treatment of up to two lesions in one or two major coronary arteries (1 target lesion in each of 2 vessels or 2 target lesions in 1 vessel). The target vessel diameter must be >/= 2.25mm and -5 Target lesion length -6 The target lesion has been successfully crossed with the intracoronary guidewire which is positioned intraluminally in the distal vessel;
-7 The target lesion diameter stenosis is >50% and <100% based on a visual estimate.

## Exclusion criteria

Exclusion Criteria:;-1 ST-elevation MI within 72 hours prior to the index procedure and/or creatine kinase (CK) >2 times the local laboratory upper limits of normal on the day of the index procedure;
-2 The patient has undergone target vessel revascularization within 6 months prior to the intended enrolment procedure.
-3 Prior stent within 5 mm of target lesion(s);
-4 Ostial target lesion(s);
-5 Unprotected left main coronary disease with >/= 50% stenosis;
-6 Angiographic evidence of thrombus within target lesion(s);
-7 Total coronary occlusion or TIMI grade 0 or 1 in the target vessel;
-8 Bifurcation disease involving a side branch >/= 2 mm in diameter;
-9 Target lesion(s) within a coronary bypass graft;
-10 Significant calcification or angulation in the target vessel that, in the Investigator's opinion, may preclude stent delivery and deployment;
-11 Recipient of heart transplant;
-12 Subject with a life expectancy less than 12 months;
-13 Known allergies to the following: aspirin, any thienopyridine, heparin, cobalt chromium, contrast agent (that cannot be managed medically), or sirolimus that cannot be managed medically;
-14 The patient has contraindication to ASA or to any thienopyridine agent.
-15 Known bleeding or hypercoagulable disorder;
-16 Known or suspected active infection at the time of the study procedures;
-17 Subject has had major surgical or interventional procedures unrelated to this study within 30 days prior to this study or planned surgical or interventional procedures within 30 days of entry into this study, or planned coronary PCI through the end of the study;
-18 The patient is currently taking systemic immunosuppressant therapy;

-19 Documented left ventricular ejection fraction (EF) < 25%;
-20 Impaired renal function (creatinine > 250 micromoles/l or > 2.5 mg/dl) at the time of treatment.

# Study design

## Design

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| Study phase: | 3 |
| Study type: | Interventional |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Will not start |
| Start date (anticipated): | 01-09-2008 |
| Enrollment: | 40 |
| Type: | Anticipated |

## Medical products/devices used

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|---|---|
| Generic name: | drug-eluting stent |
| Registration: | No |

# Ethics review

Approved WMO

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|---|---|
| Date: | 26-11-2008 |
| 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 |
| --- | --- |
| ClinicalTrials.gov | NCT00714883 |
| CCMO | NL24567.101.08 |