# What is the Optimal antiplatElet & anticoagulant therapy in patients with oral anticoagulation and coronary StenTing

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The study will assess the hypothesis that the combination warfarin & clopidogrel 75 mg/day is superior to triple therapy (warfarin + clopidogrel 75mg/day + aspirin 80mg/day) with respect to bleeding complications while equally safe with respect...

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Cardiac disorders, signs and symptoms NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON35700

**Source**
ToetsingOnline

**Brief title**
WOEST Trial:

### Condition

- Cardiac disorders, signs and symptoms NEC

**Synonym**
Atrial fibrillation = Heart rhythm disorder ; percutaneous coronary intervention= stenting

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Sint Antonius Ziekenhuis

**Source(s) of monetary or material Support:** er is geen financiering voorzien in dit onderzoek

## Intervention

**Keyword:** Atrial fibrillation, Bleeding complications, Percutaneous coronary stenting, Triple therapy

## Outcome measures

### Primary outcome

The combined end point of minor, moderate or major bleeding complications

during the initial hospitalization & one year follow-up.

### Secondary outcome

The combined event of death, myocardial infarction, stroke, systemic

embolisation & target vessel revascularisation and the individual components of

the composite primary and secondary endpoints.

# Study description

### Background summary

Chronic oral antithrombotic treatment is necessary in patients with mechanical heart valves and in the majority of patients with atrial fibrillation. When these patients have to undergo Percutaneous Coronary Intervention (PCI) with stenting, there is also an indication for treatment with aspirin and clopidogrel. However, triple therapy is known to augment the risk for bleeding complications.
Unfortunately, no prospective data are available to solve this issue. Nevertheless, it all comes down to finding the ideal therapy in patients with both atrial fibrillation and percutaneous intervention to prevent thrombotic complications (e.g. stentthrombosis) without increasing the risk of bleeding.
This prospective randomised study will assess the hypothesis that in patients on warfarin therapy and indication for elective percutaneous intervention, the combination warfarin & clopidogrel 75 mg/day is superior to triple therapy treatment in reducing the risk of bleeds while equally safe with respect to the prevention of thrombotic complications

After thorough review of the literature we expect no difference in efficiency and safety with respect to the prevention of thrombotic complications. So this is a unique opportunity to prove that dual therapy is superior to triple therapy in this context.

### Study objective

The study will assess the hypothesis that the combination warfarin & clopidogrel 75 mg/day is superior to triple therapy (warfarin + clopidogrel 75mg/day + aspirin 80mg/day) with respect to bleeding complications while equally safe with respect to the prevention of thrombotic complications in patients with both indications for warfarin use and dual antiplatelet (clopidogrel 75mg/day + aspirin 80mg/day) treatment.

### Study design

This is a prospective randomised trial in which at least n=496 patients will be recruited. We will investigate the effect of the combination warfarin-clopidogrel versus triple therapy in patients with an indication for oral anticoagulant therapy use who undergo elective PCI treatment. Patients who meet the inclusion criteria will be randomised to one of both groups. follow up is sceduled after 30 days and after 1 year.

### Intervention

only patients sceduled for PCI can be included tough this intervention would also take place without this study. What we want to study is the difference in outcome after a little change in the antithrombotic treatment

### Study burden and risks

For this patient, participating to this study does not imply any additional risk because we only compare two treatments that are frequently used in daily practice.

## Contacts

**Public**
Sint Antonius Ziekenhuis

Koekoekslaan 1
3435 CM Nieuwegein
NL
**Scientific**

Sint Antonius Ziekenhuis

Koekoekslaan 1
3435 CM Nieuwegein
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Patient under warfarin treatment such as patients with atrial fibrillation, mechanical valve...
AND with indication for percutaneous coronary intervention

## Exclusion criteria

cardiogenic shock, contra-indication for aspirin or clopidogrel, documented peptic ulcer disease within the previous six months, pregnancy and previous intracerebral haemorrhage or significant thrombocytopenia (platelet count < 50x10 9/L).

# Study design

## Design

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| Study phase: | 4 |
| Study type: | Interventional |
| Intervention model: | Parallel |

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| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-05-2008 |
| Enrollment: | 496 |
| Type: | Anticipated |

## Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | ASCAL |
| Generic name: | Acetylsalicylic acid |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |
| Brand name: | Aspro |
| Generic name: | Acetylsalicylic acid |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |
| Brand name: | Marcoumar |
| Generic name: | fenprocoumon |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |
| Brand name: | Plavix |
| Generic name: | clopidogrel |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |
| Brand name: | Sintrom |
| Generic name: | acenocoumarol |
| Registration: | Yes - NL intended use |

## Ethics review

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| Approved WMO Date: | 16-09-2008 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 07-05-2009 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 07-07-2009 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 20-07-2009 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 01-09-2009 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 05-11-2009 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 30-11-2009 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO | |

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| Date: | 14-12-2009 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 17-05-2010 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 22-07-2011 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

# 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 | EUCTR2008-001771-29-NL |
| CCMO | NL20832.100.08 |