

# Comparative study of the stability of oral anticoagulant therapy using phenprocoumon or warfarin.

|                                        |                                                       |                                                      |
|----------------------------------------|-------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>20/12/2005   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>20/12/2005 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>02/09/2008       | <b>Condition category</b><br>Haematological Disorders | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                       | <input type="checkbox"/> Results                     |
|                                        |                                                       | <input type="checkbox"/> Individual participant data |
|                                        |                                                       | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

P99-134; NTR319

## Study information

Scientific Title

**Study objectives**

Long acting coumarin derivatives can reach a more stable anticoagulant effect. Short acting coumarins are more easy to adjust. The half-life of warfarin lies between the half-life of acenocoumarol and phenprocoumon and can thereby possibly have the advantage of long acting coumarins as well as the advantage of short acting coumarins.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval received from the local medical ethics committee

**Primary study design**

Interventional

**Study design**

Randomised, active controlled, parallel group trial

**Study type(s)**

Not Specified

**Health condition(s) or problem(s) studied**

Anticoagulant treatment

**Interventions**

1. Treatment group: oral anticoagulant treatment with warfarin
2. Control group: oral anticoagulant treatment with phenprocoumon

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Phenprocoumon, warfarin

**Primary outcome(s)**

Time spent within therapeutic range, time to the first international normalised ratio (INR) in range, percentage of INRs above range after initiation scheme, reaction of INR to interruption of coumarin or vitamin K administration.

**Key secondary outcome(s)**

1. Bleeding complications
2. Thrombotic complications

**Completion date**

31/12/2006

# Eligibility

## Key inclusion criteria

1. No current use of anticoagulants
2. Aged 18 to 85 years
3. Indication for the use of oral anticoagulants
4. Living in the working area of the Leiden Anticoagulation Clinic
5. Adequate intelligence, informed consent

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 Years

## Upper age limit

85 Years

## Sex

All

## Key exclusion criteria

1. Pregnancy
2. Chemotherapy
3. Haemo- or peritoneal dialysis
4. Plasmapheresis
5. Contra-indication for the use of oral anticoagulants

## Date of first enrolment

01/03/2004

## Date of final enrolment

31/12/2006

# Locations

## Countries of recruitment

Netherlands

## Study participating centre

Leiden University Medical Centre (LUMC)

Leiden

Netherlands  
2300 RC

## Sponsor information

### Organisation

Leiden University Medical Centre (LUMC) (Netherlands)

### ROR

<https://ror.org/027bh9e22>

## Funder(s)

### Funder type

University/education

### Funder Name

Leiden University Medical Centre (LUMC) (The Netherlands)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration