ISRCTN60446748 https://doi.org/10.1186/ISRCTN60446748

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

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
02/09/2008

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof F.R. Rosendaal

Contact details
Leiden University Medical Centre (LUMC)
Department of Clinical Epidemiology
P.O. Box 9600
Leiden
Netherlands
2300 RC
+31 (0)71 5264037
f.r.rosendaal@lumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design
Randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
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.

Secondary outcome measures
1. Bleeding complications
2. Thrombotic complications

Overall study start date
01/03/2004

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
500

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)

Sponsor details
Albinusdreef 2
P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor type
University/education

Website
http://www.lumc.nl/

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
University/education

Funder Name
Leiden University Medical Centre (LUMC) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration