More precise dosing of acenocoumarol in patients aged 80 and above, a pilot study

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25342

Source
NTR

Brief title
Eighty and a half

Health condition

Atrial fibrillation, venous thrombo-embolism, heart valve repair
Boezemfibrilleren, trombose, longembolie, hartklepvervanging

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The main study parameter is quality of anticoagulation (individual time in therapeutic range and INR variability).

Secondary outcome

The secondary study parameters are treatment satisfaction, medication errors and number of INR measurements.

Study description

Background summary

More precise dosing of acenocoumarol in patients aged 80
and above, a pilot study

Study objective

We hypothesise that dosing using tablets of half a milligram acenocoumarol increases anticoagulation control

Study design

Start of study, six months later

Intervention

One group is dosed using tablets of 0.5 milligrams of acenocoumarol, while the other group uses the regular 1.0 milligram tablets. Both will be dose-adjusted to their previously determined INR target range.

Contacts

Public
UMCG
Jasper (J.H.A.) van Miert
Groningen
The Netherlands
+31503610225
Scientific
UMCG
Jasper (J.H.A.) van Miert
Groningen
The Netherlands
+31503610225

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Using acenocoumarol for any indication, and being managed by Certe Trombosedienst

- 80 years of age or older at time of inclusion

- Using acenocoumarol with an average daily dose of less than 2 milligrams in the previous three months

- Subject provided informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Initiated therapy with acenocoumarol in the last nine months

- Expected termination of VKA within six months

- Dosing step lower than or equal to "step 7", i.e. usage of less than 3.5 milligrams acenocoumarol per week. Patients who use such a low dose generally have an unfavourable prognosis.

- Patients who determine the acenocoumarol dose themselves

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-10-2017
Enrollment:	80
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	22-09-2016
Application type:	First submission

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
NTR-new	NL5905
NTR-old	NTR6093

Register	ID
Other	UMCG Research Registry : 2016 006 20

Study results