Impact of height and weight on acenocoumarol and phenprocoumon dose needed

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To collect information of 1000 patients per coumarin (acenocoumarol and phenprocoumon) to investigate the impact of height and weight on the dose needed. The database will also contain other information of the patient, like age, gender and genotypes...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON32954

Source
ToetsingOnline

Brief title
pre-EU-PACT study

Condition

- Cardiac arrhythmias
- Embolism and thrombosis

Synonym
atrial fribrillation, Thrombosis

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: European Community's Seventh Framework

Intervention

Keyword: acenocoumarol, Pharmacogenetics, phenprocoumon

Outcome measures

Primary outcome

The impact of height and weight on the coumarin dose required. This will be

investigated with lineair regression.

Secondary outcome

The dataset will be used as validation of the already developed acenocoumarol

and phenrocoumon dosing algorithms.

Study description

Background summary

The narrow therapeutic range of coumarins and an unpredictable response due to large intra- and inter-patient variability makes careful patient monitoring necessary. The principal covariates, which together account for 35-50% of the variability, are polymorphisms in genes encoding for cytochrome P450 2C9 (CYP2C9) and vitamin K epoxide reductase complex 1 (VKORC1). It is not known whether genotype-guided dosing during induction and maintenance therapy of coumarins will increase the efficacy and safety of the treatment. This will be investigated in the EU-PACT trial. The effect of height and weight on the needed acenocoumarol and phenprocoumon is unknown. In the pre-EU-PACT study we will investigate whether lenght and weight should be included or not in the dosing algorithm.

Study objective

To collect information of 1000 patients per coumarin (acenocoumarol and phenprocoumon) to investigate the impact of height and weight on the dose needed. The database will also contain other information of the patient, like age, gender and genotypes of CYP2C9 and VKORC1 and will be used for the development of the dosing algorithms for the EU-PACT trial.

Study design

This is a retrospective follow-up study.

Study burden and risks

The only burden of the study for the patient is communicating their height and weight. There are no risks associated with participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

INR target between 2.5 and 3.5
18 years or older
no participation at vitamin K study (VIKS2A)

Exclusion criteria

Pregnancy or lactation
Severe cognitive impairment

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2009
Enrollment:	2000
Type:	Actual

Ethics review

Approved WMO

Date:	24-08-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO

Date:	07-09-2009
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL28364.058.09