Dabigatran trough levels in elderly patients: are these increased, and to what extent? A pilot study.

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Objective of the study is to measure dabigatran trough levels, percentage of dabigatran glucuronidation, and diluted thrombin time, to test whether these levels are different in elderly patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational invasive

Summary

ID

NL-OMON50084

Source
ToetsingOnline

Brief title
Dabigatran trough levels in elderly.

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Cardiac arrhythmias
- Gastrointestinal haemorrhages NEC

Synonym
bleeding risk, prolonged clotting time

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

Source(s) of monetary or material Support: Catharina ziekenhuis: geriatrie + algemeen klinisch laboratorium

Intervention

Keyword: Dabigatran, Elderly, Trough level

Outcome measures

Primary outcome

Primary parameter is the dabigatran trough level, which will be analyzed by

multivariate linear regression, with age and renal function as covariates.

Besides this, also median values per age category (< 75, 75-85 and > 85 years)

will be shown and compared. Because of correction for dose, all concentrations

will be shown als ng/ml/mg.

Secondary outcome

Secondary outcomes are:

1) the percentage of each age group having dabigatran trough levels higher than

150 ng/ ml;

2.) the amount and percentage of glucuronidated dabigatran, and relation to the

age of the patient;

3.) the clotting time as diluted thrombin time and it's relation to dabigatran

level and to the amount of glucuronidated dabigatran.

Study description

Background summary

Many elderly patients need to use anticoagulants. The new group of oral anticoagulant medicins has some important benefits for elderly patients when compared to the current treatment with acenocoumarol or fenprocoumon. But,

since elderly patients have higher bleeding risk when using anticoagulants, many physicians hesitate to start the new direct oral anticoagulants in very old patients. Results of previous studies show that dabigatran trough levels vary a lot between patients, and on average levels are higher in elderly. It is also known that the risk of gastrointestinal bleedings is higher in elderly, and the age-related increase in the number of bleedings is even larger in elderly using dabigatran than in patients on warfarin. Because of this, extra precaution is needed in the elderly patients. The best plasma concentration for having best stroke prevention on the one hand and the lowest bleeding risk on the other hand, is not clear yet. But there is some evidence that when trough levels are higher than 150 ng /ml the risk of bleeding is increasing much, while not much extra reduction of stroke risk is gained.

Study objective

Objective of the study is to measure dabigatran trough levels, percentage of dabigatran glucuronidation, and diluted thrombin time, to test whether these levels are different in elderly patients.

Study design

The study has an observational design. One blood sample is taken from every patient for measuring a dabigatran trough level and the other tests as mentioned before.

Study burden and risks

Patients visit the hospital once for about one and a half hour. After giving informed consent, they will answer a few questions about medical history, medication use and weight, and the blood sample will be taken. The burden and risks are very small. There is no direct benefit for the patient himself. The benefit on population level is the increase of knowledge about pharmacokinetics of this quite new anticoagulant in elderly patients. But, in case the measured level would be elevated very much, the patient and prescribing doctor will be informed and the dose can be adjusted.

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

Outpatients from cardiology or geriatric clinic.
Dabigatran use since at least 1 week.
Dabigatran dose 2 times daily, 110 or 150 mg.
Indication for dabigatran: atrial fibrillation.

Exclusion criteria

Use of trombocyte aggregation inhibitors.
Use of PgP inhibitors.
Limitation in renal function, clearance (CKD-epi) < 30 ml/min.
Elevation of liver transaminases above 2 x upper limit of normal.
Malignancy.
Body weight below 50 kilograms or above 110 kilograms.
Incapacitated patients.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-08-2017
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	29-05-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-05-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-09-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-01-2019
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
CCMO	NL59428.100.16