Decentralized INR study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON36026

Source
ToetsingOnline

Brief title
Decentralized INR study

Condition

- Other condition

Synonym
diep vein thrombosis, prevention, pulmonary embolism, thrombosis

Health condition

het betreft patiënten die op de afdeling cardiologie behandeld worden met antistollingsmiddelen ter preventie van trombotische aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Instrumentation

Laboratory levert reagentia,Noyons stipendium (wetenschappelijke prijs klinische chemie) wordt gebruikt voor reagentia;Roche Diagnostics;Instumentation Laboratory en Siemens Healthcare leveren benodigdheden voor laboratorium bepalingen;het LAKC en de afdeling cardiologie leveren menskracht.,Roche Diagnostics levert reagentia,Siemens Healthcare levert reagentia

Intervention

Keyword: assay, decentralized, INR, point-of-care

Outcome measures

Primary outcome

Using error grid analysis1 a maximal allowable bias of 20% between the

reference method and another INR assay will be allowed.

Secondary outcome

Discrepancies between assays will be investigated by measuring coagulation

factor levels and, if present, the anti-Xa activity due to the presence of

heparin or LMWH.

Study description

Background summary

Oral anticoagulant (OAC) treatment is based upon a laboratory assay, the prothrombin time (PT), expressed as international normalised ratio (INR) to standardize the PT results between reagents of various companies. The INR for clinical patients in the AMC is presently measured centrally at the Laboratory General Clinical Chemistry (LAKC) with a regular INR assay (in-house method), which results in turn-around-times of the lab. result of approximately one hour after sample arrival. Already some years, Point-of-care testing (POCT) of the INR is available, but is solely in use for the outpatient situation. Also, in spite of the INR standardization, the INR results vary somewhat between regular INR assays because the reagents in use have different sensitivities for coagulation factor levels in the patient plasma and because some reagents contain heparinase to reduce the effect of co-medication with heparin or low-molecular-weight heparin (LMWH). Proper evaluation of the POCT and the regular INR assays with the reference method (WHO reagent and manual tilt tube

assay) has not yet been performed with material derived from hospitalised patients.

Study objective

The aims are: 1. Test whether a POCT INR can be used in a clinical setting compared to five regular central assays (including the in-house method) and with the tilt tube / WHO standard as reference INR. 2. To establish possible causes for differences between the regular INR assays and with the POC test.

Study design

The nurses of the Cardiology department will collect 2.7 ml venous blood (plus an additional 5.4 mL) for the regular laboratory assays as usual and perform an extra *finger prick* for the POCT INR. Anticoagulant co-medication (heparin or low-molecular-weight heparin [LMWH] levels) will be determined in all venous blood samples, and coagulation factor levels in samples with discrepant INR assay results.
Study population: Patients who stay at the Cardiology department and undergo oral anticoagulation therapy.

Study burden and risks

Patients will have an additional capillary blood drawn from their finger, plus 5.4 mL extra venous blood collection, performed during the routine sampling in patient care.

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

Treated with anticoagulation medication
Inpatient in cardiology department

Exclusion criteria

No fingers available for fingerprick
Terminally ill

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-09-2011

Enrollment:	1036
Type:	Actual

Ethics review

Approved WMO Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL36304.018.11