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ICAD: Clinical validation study of a new algorithm for oral anticoagulant dosing

Submission date	Recruitment status	[_] Prospectively registered
26/09/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/09/2008	Haematological Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
P02-089; NTR724

Study information

Scientific Title

Acronym
ICAD

Study objectives
The equations used by most current algorithms are usually based on a simple pharmacodynamic model, which implies a linear function between the international normalised ratio (INR) and the dosage. Our new algorithm consists of two sub-models in which the first sub-model describes the collective influence of all processes on the effect of the vitamin K antagonist and the second sub-model describes the relationship between the dosage and the corresponding INR. The second sub-model includes a variable parameter to reflect the sensitivity of the patient that may change over time. Because of the inclusion of a parameter that reflects the sensitivity of the patient we think it is better capable of proposing a dosage that leads to an INR within the therapeutic range.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Anticoagulant treatment

Interventions
Oral anticoagulant dosage supported by the new algorithm (ICAD) and oral anticoagulant dosage supported by the standard algorithm (TRODIS).

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
1. Percentage of time therapeutic range
2. Proportion of visits in which the algorithm gave a proposal
3. Proportion that was accepted by the physician

Secondary outcome measures
1. Mean time between visits
2. Bleeding events
3. Thrombotic events

Overall study start date
14/08/2003

Completion date
01/09/2004

Eligibility

Key inclusion criteria
1. Indication for long term anticoagulant therapy
2. Aged between 18 and 80

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
712

Key exclusion criteria
1. Participation in the patient self-management program
2. Staying long periods abroad
3. Terminal stage of disease

Date of first enrolment
14/08/2003

Date of final enrolment
01/09/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Center (LUMC)
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Center (LUMC) (The Netherlands)

Sponsor details
Albinusdreef 2
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05xvt9f17

Funder(s)

Funder type
Industry

Funder Name
Foundation Bazis (now known as iSOFT) (The Netherlands)

Funder Name
Dutch Thrombosis Foundation (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/05/2005		Yes	No