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Randomised comparison of anticoagulation control and monitoring with versus without laboratory-provided computerized decision support

Submission date 08/11/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 25/11/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 14/09/2009	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

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
N/A

Study information

Scientific Title

Study objectives
Laboratory-provided computerized decision support will improve anticoagulation control relative to usual care

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yes, August 2001

Study design
Cluster-randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Various

Interventions
Anticoagulation control and monitoring with versus without laboratory-provided computerized decision support (CDS)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Acceptability of the CDS service, as assessed by the proportion of physicians who would continue to use it if offered
2. Estimated effectiveness, as assessed by percentage of time within target INR range

Secondary outcome measures
Hemorrhagic and thromboembolic events requiring hospital attendance

Overall study start date
01/01/2002

Completion date
30/06/2003

Eligibility

Key inclusion criteria
Physicians:
1. Family or general practitioner
2. Full-time office practice
3. Practice address within study laboratory catchment area
4. At least 3 eligible patients willing to participate

Patients:
1. On long-term warfarin therapy
2. Using the study laboratory for international normalized ratio (INR) tests and expecting to continue to do so for at least 12 months

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Physicians: 40; Patients: 380

Key exclusion criteria
None

Date of first enrolment
01/01/2002

Date of final enrolment
30/06/2003

Locations

Countries of recruitment
Canada

Study participating centre
ICES
Toronto, Ontario
Canada
M4N 3M5

Sponsor information

Organisation
Ontario Program for Optimal Therapeutics (Canada)

Sponsor details
105 Main Street E, Level One
Hamilton, Ontario
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Sponsor type
Not defined

ROR
https://ror.org/00tjpb250

Funder(s)

Funder type
Not defined

Funder Name
Ontario Program for Optimal Therapeutics (Canada)

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