

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	<input type="checkbox"/> Prospectively registered
Registration date 25/11/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/09/2009	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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