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Optimising thromboembolic and stroke prevention in pharmacist-managed oral anticoagulotherapy

Submission date	Recruitment status	[_] Prospectively registered
05/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/03/2009	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Lyne Lalonde

Contact details
Équipe de recherche
Soins de première ligne
Centre de santé et de services sociaux de Laval (Cité de la Santé de Laval)
1755 René-Laennec
Local D-S145
Laval
Canada
H7M 3L9
+1 514 343 6111 ext. 5315
lyne.lalonde@umontreal.ca

Additional identifiers

Protocol serial number
UCT-58955

Study information

Scientific Title
Optimising thromboembolic and stroke prevention: a randomised controlled trial of pharmacist-managed oral anticoagulotherapy

Acronym
PHARMA

Study objectives
Compared to the centralised care model, the integrated care model may be associated with similar anticoagulation control, similar incidence of major haemorrhagic and thromboembolic events and similar patients quality of life. However, the integrated care may represent a more efficient use of the health-care system. It may be less costly.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cité de la Santé de Laval, Comité d'éthique et de la recherche (conditional approval of the project: 18th December 2001). Full approval as on 12th November 2002 until 11th November 2003; amendments to the protocol made on 16th September 2003. Reapprobation of the project on the following dates:
18th November 2003: reapprobation of the project until 11th November 2004
9th October 2004: reapprobation of the project until 15th September 2005
11th October 2005: reapprobation of the project until 11th November 2006

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Thromboembolism and stroke

Interventions
A three-year randomised controlled trial (RCT) will be conducted. All patients registering at the PMAS with a first prescription of warfarin for a minimum of six months and who agree to participate (n = 500) will be randomised to the integrated or the centralised PMAS model of care.

Integrated care model: Patients will be monitored by PMAS pharmacists until stabilisation of their international normalised ratio (INR) within their prescribed therapeutic range (six to eight weeks). Thereafter, they will be transferred to their treating physician.

Centralised care model: Patients will be monitored by PMAS for the entire duration of the study.

All patients will be followed for a total of six months. We will monitor the quality of INR control, the incidence of major thromboembolic and haemorrhagic events, the patients health-related quality of life, and direct health-care costs associated with each model of care.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Warfarin

Primary outcome(s)
The percentage of time spent within the target INR range.

Key secondary outcome(s)
1. Incidence and severity of major thromboembolic and haemorrhagic events
2. Health-related quality of life
3. Direct medical-care costs

Completion date
31/03/2005

Eligibility

Key inclusion criteria
1. The patient is referred to the Pharmacy Managed Anticoagulation Service (PMAS) with a prescription of warfarin for at least six months
2. The patient is aged 18 years and older, either sex
3. The patient agrees to go to the Cité de la Santé de Laval, the Centre Hospitalier Ambulatoire Régional de Laval, or one of the four Laval Centre Local de Services Communautaire for blood drawing during participation in the study (six months)
4. The patient lives in the Laval area
5. The patient is able to read and speak French or English
6. The patient agrees to participate in the study and has signed the informed consent form
7. The patient's treating physician has agreed to participate and has signed the informed consent form
8. It is expected that the patient will be transferred to the treating physician

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex

All

Key exclusion criteria
1. The patient participates to another study
2. The patient is referred to the PMAS for a pre-admission

Date of first enrolment
01/01/2001

Date of final enrolment
31/03/2005

Locations

Countries of recruitment
Canada

Study participating centre
Équipe de recherche
Laval
Canada
H7M 3L9

Sponsor information

Organisation
Cité de la Santé de Laval (Canada)

ROR
https://ror.org/041v96n47

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: UCT-58955)

Funder Name
Taro Pharmaceutical Inc. (Canada)

Results and Publications

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	01/07/2008		Yes	No