Assessment of anticoagulant control in primary care using near patient testing and computerised decision support.

Submission date	Recruitment status No longer recruiting	Prospectively registered		
23/01/2004		Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/01/2004	Completed	[X] Results		
Last Edited 01/12/2009	Condition category Circulatory System	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PSI03-08

Study information

Scientific Title

Study objectives

Objectives of this study were to test the efficacy, cost effectiveness and safety of using a nurse-led clinic in primary care, involving near patient testing (NPT) and computerised decision support software (CDSS) for therapeutic oral anticoagulation management. The null hypothesis tested was that anticoagulation care can be provided at least as well in primary care as compared to routine hospital management based on a variety of previously validated and novel clinical outcome measures.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Other

Participant information sheet

Health condition(s) or problem(s) studied

Thromboembolic disease

Interventions

A randomised controlled trial using 12 primary care practices in Birmingham, UK (9 intervention and 3 control). The study used 2 control populations; patients individually randomly allocated as controls in the intervention practices (intra-practice controls), and all patients in the 3 control practices (inter-practice controls), included to estimate any Hawthorne effect amongst the intervention controls. Patients from the 9 intervention practices were randomised to intervention (practice based anticoagulation clinic) or control (traditional attendance at hospital clinic).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The main outcome measure used was INR control determined by; number of tests performed within target INR range; point prevalence of patients achieving individual therapeutic INR targets; and individual proportion of time spent within therapeutic target range.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/1994

Completion date

30/04/1997

Eligibility

Key inclusion criteria

Patients receiving warfarin therapy (n=368)

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

368

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/10/1994

Date of final enrolment

30/04/1997

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
The Department of Primary Care and General Practice
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

NHS Primary and Secondary Care Interface National Research and Development Programme (UK)

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	01/08/2000		Yes	No