ISRCTN92166461 https://doi.org/10.1186/ISRCTN92166461

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

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

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
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
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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