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

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

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

**Prof FDR Hobbs** 

#### Contact details

The Department of Primary Care and General Practice Medical School
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT
+44 (0)121 414 3765
f.d.r.hobbs@bham.ac.uk

#### Additional identifiers

Protocol serial number

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

#### Study type(s)

Other

#### 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(s)

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.

#### Key secondary outcome(s))

Not provided at time of registration

#### Completion date

30/04/1997

# **Eligibility**

#### Key inclusion criteria

Patients receiving warfarin therapy (n=368)

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

#### 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

**United Kingdom** 

England

# 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)

# Funder(s)

#### Funder type

Government

#### **Funder Name**

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

### **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	01/08/2000		Yes	No