

A randomised controlled trial of patient self management of oral anticoagulation compared to standard care

Submission date 23/10/2000	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 23/10/2000	Overall study status Completed	☒ Protocol
Last Edited 21/07/2011	Condition category Haematological Disorders	☐ Statistical analysis plan
		☒ Results
		☐ 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

Protocol serial number

G9900263

Study information

Scientific Title

Acronym

SMART: Self-Management of Anticoagulation, a Randomised Trial

Study objectives

The null hypothesis is that patients managing their own anticoagulation can achieve as good therapeutic control as patients receiving standard care.

Please note that as of 07/02/2007 this record was updated to include the current target number of participants. The previous target number of participants at the time of registration was 660.

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)

Not Specified

Health condition(s) or problem(s) studied

Anticoagulant therapy

Interventions

The intervention comprises a training programme to enable patients to undertake oral anticoagulation monitoring at home.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Therapeutic international normalised ratio (INR) control
2. Bleeding and thrombotic complications

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/06/2003

Eligibility

Key inclusion criteria

All patients aged over 18 receiving warfarin therapy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/09/2000

Date of final enrolment

30/06/2003

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**

Medical Research Council (MRC) (UK)

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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	05/11/2005		Yes	No
Results article	results	01/04/2011		Yes	No
Protocol article	protocol	18/09/2003		Yes	No