ISRCTN19313375 https://doi.org/10.1186/ISRCTN19313375

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

Registration date
23/10/2000

Overall study status
Completed

Last Edited
21/07/2011

Condition category
Haematological Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2000

Completion date
30/06/2003

Eligibility

Key inclusion criteria
All patients aged over 18 receiving warfarin therapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
512

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
England

United Kingdom

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

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.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, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

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