ISRCTN35571063 https://doi.org/10.1186/ISRCTN35571063

QAASM: an evaluation of three methods of external quality assurance for patient self-management of oral anticoagulation

Submission date
11/02/2003

Recruitment status
No longer recruiting

Registration date
11/02/2003

Overall study status
Completed

Last Edited
15/08/2008

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] 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

Contact name
Ms Ellen Murray

Contact details
Department of Primary Care and General Practice
University of Birmingham
Edgbaston
United Kingdom
B15 2TT
+44 (0)121 414 3761
e.t.murray@bham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G106/970

Study information

Scientific Title

Acronym
QAASM

Study objectives
Aim:
To evaluate three different methods of external quality assurance (EQA) for home management.

Primary objective:
To compare patients' treatment related quality of life in relation to external quality assurance for home anticoagulation management, with or without supervision.

Secondary objective:
To compare three different methods of EQA, one unsupervised and two supervised in terms of:
1. Reliability of EQA results
2. Impact on international normalised ratio (INR) control
3. Costs associated with each method of EQA

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

Patients from the SMART trial (Self-management of warfarin: a randomised trial) will be randomly allocated to two main groups at practice level for supervised or non-supervised External Quality Control (EQA). Twenty-four practices into groups 1 and 2.

The practices randomised to supervised EQA will then be further randomly allocated to different methods of supervised EQA, Groups 2A and 2B.

Unsupervised group: formal EQA scheme (National Quality Assessment Scheme NEQAS).

Supervised groups: International normalised ratio (INR) results from venous samples sent to the local laboratory will be compared with contemporaneous near patient testing (NPT) capillary samples at the practice using the patient's NPT system, or INR results from patient NPT system capillary sample tests will be compared to results from an NPT system weekly quality control tested using samples from NEQAS at the practice, NPT to NPT.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Difference in treatment related quality of life scores between non supervised and supervised EQA models

Secondary outcome measures
1. Comparison of EQA results between three models of EQA
2. Comparison of therapeutic INR control in terms of the percentage of time spent within therapeutic range
3. Cost comparison of EQA models

Overall study start date
01/08/2000

Completion date
31/07/2004

Eligibility

Key inclusion criteria
1. Patients aged 18 or over
2. A long term (greater than 12 months) indication for oral anticoagulation
3. Have taken warfarin for at least six months
4. Are willing (or in the case of dependent patients both they and their carer are willing) to participate in the study

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
260

Key exclusion criteria
1. Patients with a short-term indication (less than 12 months) for warfarin therapy
2. Aged under 18 years
3. Housebound patients
4. Patients confined to a nursing home

Date of first enrolment
01/08/2000

Date of final enrolment
31/07/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Primary Care and General Practice
Edgbaston
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 (MRC) (UK) - Special Training Fellowship in HSR

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	01/11/2002		Yes	No