

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	<input type="checkbox"/> Prospectively registered
Registration date 11/02/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/08/2008	Condition category Haematological Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Department of Primary Care and General Practice

Edgbaston

United Kingdom

B15 2TT

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK) - Special Training Fellowship in HSR

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	01/11/2002		Yes	No