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Decision Analysis in Routine Treatment II: a randomised controlled trial (efficacy study) of a decision aid to support shared decision making for patients with atrial fibrillation

Submission date
06/11/2002

Recruitment status
No longer recruiting

Registration date
06/11/2002

Overall study status
Completed

Last Edited
27/11/2012

Condition category
Circulatory System

[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
065131

Study information

Scientific Title

Acronym
DARTS II

Study objectives
To determine the efficacy of implicit and explicit decision support tools in reducing decision conflict under ideal circumstances.

To support design of a subsequent multi-centre pragmatic randomised controlled trial.

The initial study design was a three arm open randomised controlled trial comparing explicit and implicit decision support tools with paper based guidelines. The explicit arm was discontinued in October 2003.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Atrial fibrillation

Interventions

Patients randomised to one of three interventions:
1. Explicit DARTS tool - full shared decision making tool
2. Implicit DARTS tool - shortened version of shared decision making tool
3. Evidence based guidelines group - control arm

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary outcome measure is the decision conflict scale. Prior to clinic attendance patients will complete scales on decision conflict, their choice predisposition, knowledge, decision making preference, general anxiety and risk factors/demographic information.

Immediately following the clinic, patients will complete scales on decision conflict, knowledge, decision making role experienced, and anxiety.

At three months, patients will be sent follow-up postal questionnaires including the decision conflict scale, decision making preference scale and the knowledge scale.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/11/2001

Completion date
30/11/2004

Eligibility

Key inclusion criteria
Patients aged over 60 with non-valvular atrial fibrillation on aspirin, warfarin or no anti-thrombotic treatment

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
109

Key exclusion criteria

1. Acute onset requiring cardiological referral for consideration of cardioversion
2. Had a previous stroke or Transient Ischaemic Attack (TIA)
3. Have absolute contraindications to warfarin
4. Suffer from dementia or cognitive impairment sufficient to hinder shared decision making

Date of first enrolment
01/11/2001

Date of final enrolment
30/11/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Population and Health Sciences
Newcastle upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Trust (UK)

Sponsor details
Research and Development Department
Room 3, The Bridge, Peacock Hall
Royal Victoria Infirmary
Queen Victoria Road
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Sponsor type
Hospital/treatment centre

Website

http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 065131)

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	01/06/2007		Yes	No
Results article	Results of qualitative process evaluation	01/06/2007		Yes	No