# 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	Recruitment status No longer recruiting	Prospectively registered	
06/11/2002		☐ Protocol	
Registration date 06/11/2002	Overall study status Completed	Statistical analysis plan	
		[X] Results	
<b>Last Edited</b> 27/11/2012	Condition category Circulatory System	[] 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

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

## Study type(s)

**Not Specified** 

# 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(s)

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.

## Key secondary outcome(s))

No secondary outcome measures

## Completion date

30/11/2004

# **Eligibility**

## Key inclusion criteria

Patients aged over 60 with non-valvular atrial fibrillation on aspirin, warfarin or no antithrombotic treatment

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Senior

## Sex

All

## 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

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)

## **ROR**

https://ror.org/05p40t847

# Funder(s)

## Funder type

Charity

## Funder Name

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

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