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A study of impact and outcome of a structured educational package on patients starting warfarin therapy

Submission date 05/09/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/10/2009	**Overall study status** Completed	
Last Edited 27/04/2018	**Condition category** Other	

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
N/A

Study information

Scientific Title
A randomised controlled trial of a structured educational programme for patients starting warfarin therapy

Study objectives
The purpose of this study was to examine the relationship between knowledge, satisfaction and compliance to the administration of a structured educational package for patients starting warfarin therapy and its effects on safety. No prediction on outcome was made prior to conducting the research.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Mid Staffordshire Local Research Ethics Committee, 20/04/2000

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Education for patients starting warfarin therapy

Interventions
In-patients started on warfarin during admission were randomised into a Control Group or an Experimental Group.

Control Group received the 'usual care'.

Experimental Group received a structured educational package which included structured counselling regarding their treatment by the study co-ordinator; and the opportunity to view a video "Living with Warfarin. A Guide for Patients" (St George's Hospital Medical School) as many times as they felt necessary, a copy of which was also available for the patient to take home if required.

General information handouts available were the same for both study groups. All patients then completed an anticoagulant questionnaire prior to discharge to reflect the knowledge considered essential for safe therapy.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Warfarin

Primary outcome measure
Level of knowledge assessed by a questionnaire at discharge (0 months) and 3 months post-discharge

Secondary outcome measures
1. Satisfaction with the complete package of care assessed by a questionnaire at 3 months post-discharge
2. Percentage of INR readings within target range at 6 months (measured over 6 months)

Overall study start date
01/09/2000

Completion date
01/06/2001

Eligibility

Key inclusion criteria
1. Both males and females, adult (over 16 years)
2. The patient was taking warfarin for the first time or as a new episode
3. The patient or individual supervising the treatment had appropriate capacity and was able to read, speak and write English
4. The patient would be maintained on warfarin therapy for at least 3 months

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
45

Key exclusion criteria

1. They resided in a nursing or residential home where warfarin therapy would be supervised by a health professional
2. They were themselves a health professional
3. They had been commenced on warfarin at another hospital prior to follow-on admission to the Stafford Hospital (where they would have already received a different education package)
4. They were started on warfarin in Accident and Emergency and discharged home without formal hospital admission

Date of first enrolment
01/09/2000

Date of final enrolment
01/06/2001

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Stafford Hospital, Department of Haematology
Weston Road
Stafford
United Kingdom
ST16 3SA

Sponsor information

Organisation
Mid Staffordshire NHS Foundation Trust

Sponsor details
Stafford Hospital
Weston Road
Stafford
England
United Kingdom
ST16 3SA

Sponsor type
Hospital/treatment centre

Website

http://www.midstaffs.nhs.uk/

Funder(s)

Funder type
Government

Funder Name
Local departmental budget at Mid Staffordshire Hospitals NHS Trust (UK)

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	01/08/2014		Yes	No