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Improving the safety and efficacy of anticoagulation therapy

Submission date 21/10/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 21/10/2010	**Overall study status** Completed	
Last Edited 30/09/2016	**Condition category** Haematological Disorders	

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
8579

Study information

Scientific Title

Improving the safety and efficacy of anticoagulation therapy for thromboembolic disease through vitamin K: a single centre randomised controlled trial

Study objectives
To investigate whether daily supplementation with vitamin K improves the stability of anticoagulation control in patients on chronic therapy with warfarin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sunderland Research Ethics Committee, 08/06/2009, ref: 09/H0904/25

Study design
Single-centre non-randomised observational screening cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Not specified

Study type(s)
Screening

Participant information sheet
Not available in web format, please contact Maggie Fearby on +44 (0)191 282 1632 to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Blood; Subtopic: Blood (all Subtopics); Disease: Non-malignant haematology

Interventions
Randomised (blinded) to vitamin K/placebo 150 µg orally once daily for 6 months. Follow-up at 1, 2, 4, 8, 12, 16, 20, and 24 weeks post initial dose.

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vitamin K

Primary outcome measure

Percent time within target INR (calculated by the method of interpolation) for the study period, measured at baseline and weeks 1, 2, 4, 8, 12, 16, 20 and 24 weeks.

Secondary outcome measures
1. Clinical events of major (defined as bleeding that led to loss of 2 units of blood over a 7 day period
2. Days attending anticoagulation clinic to monitor and achieve target International Normalised Ratio (INR)
3. Markers of lack of efficacy including recurrent thrombosis
4. The number of warfarin dose changes
5. Quality of life questionnaires recorded at baseline and repeated at the end of the study

Overall study start date
01/07/2010

Completion date
01/01/2013

Eligibility

Key inclusion criteria
1. Long term warfarin therapy
2. Aged greater than or equal to 18 years
3. Male and female

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 180

Key exclusion criteria
1. Abnormal hepatic or renal function
2. Impairment of cognitive function

Date of first enrolment
01/07/2010

Date of final enrolment
01/01/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle upon Tyne Hospitals NHS Foundation Trust
Newcastle Upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
Queen Victoria Road
Newcastle Upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme

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?
HRA research summary			28/06/2023	No	No