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# Improving the safety and efficacy of anticoagulation therapy

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
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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 |