

Improving the safety and efficacy of anticoagulation therapy

Submission date 21/10/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 30/09/2016	Condition category Haematological Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Screening

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

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)

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

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