European Pharmacogenetics of Anticoagulant Therapy

Submission date	Recruitment status No longer recruiting	Prospectively registered		
29/10/2010		[] Protocol		
Registration date	Overall study status	[] Statistical analysis plan		
29/10/2010	Completed	[X] Results		
Last Edited 14/07/2014	Condition category Circulatory System	Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number 2009-016993-34

IRAS number

ClinicalTrials.gov number NCT01119300

Secondary identifying numbers

9031

Study information

Scientific Title

Acronym EUPACT

Study objectives Two-armed, single blind, randomised controlled trial of genotype guided dosing versus nongenotype guided dosing.

Ethics approval required Old ethics approval format

Ethics approval(s) MREC approved (ref: 10/H1005/51)

Study design Multicentre randomised interventional treatment trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Not specified

Study type(s) Treatment

Participant information sheet

Health condition(s) or problem(s) studied Topic: Stroke Research Network; Subtopic: Prevention; Disease: Drug type

Interventions

Genotyping for CYP2C9 & VKORC1: Predose POCT to determine genotype for CYP2C9 and VKORC1 for participants randomised in intervention group.

Follow up length: 3 months

Intervention Type Other

Phase

Phase IV

Primary outcome measure

Percent time within therapeutic INR range 2.0-3.0 during 12 weeks after start of coumarin therapy

Secondary outcome measures Not provided at time of registration

Overall study start date 04/10/2010

Completion date 22/06/2013

Eligibility

Key inclusion criteria

1. Patients with either venous thromboembolism (VTE) or atrial fibrillation (AF) requiring coumarin therapy for at least 12 weeks and a target International Normalised Ratio (INR) in the low intensity range (INR range 2 - 3)

- 2. Aged greater than or equal to 18 years, either sex
- 3. Ability to attend scheduled visits
- 4. Signed informed consent

Participant type(s) Patient

Age group Not Specified

Lower age limit

18 Years

Sex Not Specified

Target number of participants

Planned sample size: 706; UK sample size: 706

Key exclusion criteria

1. Presence of a mechanical heart valve

2. Severe cognitive impairment which affects adherence to therapy as judged by the responsible physician

- 3. Known genotype CYP2C9 or VKORC1 at start of the study
- 4. Previous or current treatment with any coumarin (maximum one dose allowed)
- 5. Pregnancy or lactation
- 6. Non-eligible subject according to the treating physician
- 7. A blood transfusion within the last two weeks or bone marrow transplantation at any time

Date of first enrolment 04/10/2010

Date of final enrolment 22/06/2013

Locations

Countries of recruitment England

Sweden

United Kingdom

Study participating centre Department of Pharmacology and Therapeutics Liverpool United Kingdom L69 3GE

Sponsor information

Organisation University of Liverpool (UK)

Sponsor details Department of Pharmacology and Therapeutics Sherrington Building The New Medical School Ashton Street Liverpool England United Kingdom L69 3GE

Sponsor type University/education

Website http://www.liv.ac.uk/

ROR https://ror.org/04xs57h96

Funder(s)

Funder type Government

Funder Name European Union (EU) (Belgium) - Seventh Framework Programme (FP7)

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?
<u>Results article</u>	results	12/12/2013		Yes	No
HRA research summary			28/06/2023	No	No