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European Pharmacogenetics of Anticoagulant Therapy

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

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
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 non-genotype 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
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Sponsor information

Organisation
University of Liverpool (UK)

Sponsor details
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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?
Results article	results	12/12/2013		Yes	No
HRA research summary			28/06/2023	No	No