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Effect of CYP2C9 and VKORC1 genotype on inter-individual warfarin dose - A prospective study in Chinese population

Submission date	Recruitment status	[_] Prospectively registered
06/06/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/07/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/06/2021	Other	

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
N/A

Study information

Scientific Title
Effect of CYP2C9 and VKORC1 genotype on inter-individual warfarin dose - A prospective study in Chinese population

Study objectives
The large inter-individual variation in the requirement for warfarin is mainly result from patients genetic background, especially polymorphisms in CYP2C9 and VKORC1 genes. Here we are going to use a computational algorithm, which is validated through retrospective data, to predict the stable dose to a given patient. Our algorithm is comprised of not only physical data of the patient, but also their genetic polymorphisms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Nan Fang Hospital Medical Ethics Committee on the 25th April 2007 (ref: 200706)

Study design
Randomised controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Not applicable

Interventions
1. Retrospective study
We enrolled 200 patients undergoing stable warfarin anticoagulation therapy. An algorithm has been established based on patients personal data including gender, age, height, weight and genotypes of CYP2C9 and VKORC1.

2. Prospective study
Treatment group: Patients stable dose will be calculated using the algorithm before they use warfarin. The first three warfarin doses will be taken according to the calculated dose. Then the doses will be adjusted depending on INR values until target INR (2.0-3.0) is obtained.

Control group: Patients use the current method to find warfarin stable dose.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Difference in stable warfarin doses among patients with genotypes CYP2C9 and VKORC1
2. An algorithm of stable warfarin dose established using multiple linear-regression equation
3. To assess the feasibility of the algorithm for treatment group compared to control group on:
3.1. Days until a stable therapeutic INR (2.0-3.0)
3.2. Days until an adverse outcome

Secondary outcome measures
1. INR, measured every day during hospitalization and twice a week after discharge
2. Warfarin dose, recorded every day
3. Adverse outcome, recorded every day

Overall study start date
01/06/2006

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Patients who will initiate warfarin administration
2. Aged 18 years or more
3. Written informed consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Total of 400 subjects, 200 for retrospective study and 200 for prospective study.

Total final enrolment
422

Key exclusion criteria
1. Patients with previous and current liver disease
2. Renal failure (creatinine greater than 106 μmo/L)
3. Base coagulant response time (INR) is 1.4 or more
4. Patients using any other known drugs that related to CYP2C9
5. Use of warfarin in the past three months

Date of first enrolment
01/06/2006

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
China

Study participating centre
Technology Centre of Prenatal Diagnosis and Genetic Testing
Guangdong
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Sponsor information

Organisation
National Natural Science Foundation of China

Sponsor details
Shuangqing Road 83
Haiding District
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China
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Sponsor type

Government

Website
http://www.nsfc.gov.cn/Portal0/default99.htm

ROR
https://ror.org/01h0zpd94

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China (National Science Fund for Distinguished Young Scholars; ref: 30325037)

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

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		01/03/2009	10/06/2021	Yes	No