

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

Submission date 06/06/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/07/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/06/2021	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Xiang-Min Xu

Contact details

Technology Centre of Prenatal Diagnosis and Genetic Testing

Nanfang Hospital

Tonghe

Guangzhou

Guangdong

China

510515

+86 20 61648293

gzxuxm@pub.guangzhou.gd.cn

Additional identifiers

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)

Primary study design

Interventional

Study design

Randomised controlled trial.

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

422

Key exclusion criteria

1. Patients with previous and current liver disease
2. Renal failure (creatinine greater than 106 $\mu\text{mo/L}$)
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

China

510515

Sponsor information

Organisation

National Natural Science Foundation of China

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 Wěiyuánhùi, , NSFC, NNSF, NNSFC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

China

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?
Results article		01/03/2009	10/06/2021	Yes	No