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Effect of polymorphic CYP2C19 genotype on the pharmacokinetics and pharmacodynamics of clopidogrel in healthy subjects

Submission date 31/07/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/09/2007	**Overall study status** Completed	
Last Edited 24/05/2019	**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

Protocol serial number
PGX-CPG-101

Study information

Scientific Title

Effect of polymorphic CYP2C19 genotype on the pharmacokinetics and pharmacodynamics of clopidogrel in healthy subjects

Study objectives
To evaluate the pharmacogenetic effect of CYP2C19 gene on the Pharmacokinetics (PK) / Pharmacodynamics (PD) of clopidogrel. The original target was the patients with cardiovascular diseases taking clopidogrel. However, due to the limitation of enrollment the trial was conducted with healthy subjects with different CYP2C19 genotype to demonstrate that the effect of clopidogrel varies according to the patient's CYP2C19 genotype.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Institutional Review Board of Anam Hospital, Korea University College of Medicine, Seoul, Korea, approved on 12 February 2007 (ref: AN-06151-001).

Study design
Open-label, parallel, multiple-dose comparative study.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cardiovascular diseases

Interventions
After a loading dose of clopidogrel (300 mg; oral), patients will take a standard dose of clopidogrel 75 mg once a day for 6 days.

The following will be carried out:
1. Assessment of PK of clopidogrel and its metabolite SR26334
2. Measurement of the inhibition of ADP induced platelet aggregation by clopidogrel for 15 days
3. Evaluation of CYP2C19 phenotyping test using omperazole hydroxylation as a CYP2C19 probe

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
CYP2C19 gene

Primary outcome(s)
Genetic association with biological effect of clopidogrel.

Key secondary outcome(s))

PK/PD relationship.

Completion date
31/08/2007

Eligibility

Key inclusion criteria
1. Healthy male subjects aged between 19 to 55
2. Wish to participate in the study
3. Informed consent for the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Total final enrolment
24

Key exclusion criteria
1. A history of or currently active clinically significant cardiac (including clinically significant abnormalities on Electrocardiogram [ECG] according to Principal Investigator [PI]), pulmonary, gastrointestinal, hepatic, renal, pancreatic, or neurological disease
2. Heavy smoker and alcohol consumer
3. Use of anticoagulants or medication within the last 1 month

Date of first enrolment
01/03/2007

Date of final enrolment
31/08/2007

Locations

Countries of recruitment
Korea, South

Study participating centre
126-1
Seoul

Korea, South
136-705

Sponsor information

Organisation
Korea University (South Korea)

ROR
https://ror.org/047dqcg40

Funder(s)

Funder type
Government

Funder Name
Anam Hospital, Korea University College of Medicine

Funder Name
The Korea Health 21 Research and Development Project, Ministry of Health and Welfare (South Korea)

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	results	01/08/2008	24/05/2019	Yes	No