

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

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>31/07/2007   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>17/09/2007 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>24/05/2019       | <b>Condition category</b><br>Circulatory System   | <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 Ji-Young Park

**Contact details**  
126-1  
Anam-dong 5-ga  
Sungbuk-gu  
Seoul  
Korea, South  
136-705  
+82 2 920 6288  
jypark21@korea.ac.kr

## 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).

### **Primary study design**

Interventional

### **Study design**

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

### **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 omeprazole 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/08/2008   | 24/05/2019 | Yes            | No              |