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TITLE OF STUDY

Downstream molecular signals of P2Y12 receptors in hyporeactive patients under clopidogrel treatment

NCT03190005 Unique Protocol ID: TCHIRB-10603117-E

PRINCIPAL INVESTIGATOR

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Taipei City hospital

Informed consent

No：TCHIRB-10603117-E Downstream molecular signals of P2Y12 receptors in hyporeactive patients under clopidogrel treatment
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Division of Cardiovascular section

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Duration:

2017/01/01- 2017/12/31

participant

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Emergency contact： phone：

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Study Purpose:

Platelet reactivity has been accepted as an indicator of the reaction of the P2Y12 inhibitor during treatment, currently, the existing evidence to support the post-treatment platelet activity can be used to distinguish the potential risk among patients who received percutaneous transluminal coronary angioplasty after ischemic / thrombotic events. The risks of stent thrombosis, of which, by analysis of the PRU (P2Y12 reaction units) value level of VerifyNow System has been considered an international standard tools. PRU value by VerifyNow system can easily and quickly showed platelet reactivity relative to short or long term risk stratification under dual antiplatelet agents(aspirin and clopidogrel) after stents implantation. High PRU response units (drug poor responders) in accordance with the 2013 publication of the European Society of Cardiology guidelines

defined of platelet function, is PRU not less than 208(≥208).

We ran a previous related plan within 2014 under the medical study project budget of the Taipei City hospital, which named "platelet reactivity as a post-percutaneous coronary stent implantation antiplatelet adjust the reference", it has been figured that responsibility under the P2Y12 receptor inhibitors were significantly different between the Taiwaneses and Caucasians (Taiwaneses revealed clopidogrel lower responsive, but stronger reaction to ticagrelor), although "low" response to clopidogrel between Taiwaneses (In fact, according to our experiments, 30 days after medication, the rate of HOTPR-High On- Treatment Platelet Reactivity; namely PRU≥208, the Taiwaneses and Caucasians are very close to each), but it has relative lower subacute stent thrombosis rate than the Caucasian at 30 days(This reaction is also known as the “Asian paradox”), according to literature known abroad because of the high prevalence of CYP2C19 point gene deletion rate among the Asians (compare with Caucasians: ~ 65% vs ~ 30%); there also suggested other possible explanations: Caucasian factor V Leiden (G1691A) and

prothrombin (G20210A) a higher proportion of mutations, on hemostatic factors (fibrinogen, d-dimer, and factor VIII) and plasma endothelial activation markers (such as von Willebrand factor, intercellular adhesion molecule 1, and E-selectin) existed differences between the races; in addition, a number of different indicators of inflammation, such as CRP. Asians show lower level CRP than the Caucasians. However, did we found the true answer? So, we designed the following experiment, through the mode of drug administration in vitro, can completely exclude the influence of the liver metabolic enzyme cytochrome P450, and observe the relevant downstream signals of P2Y12 receptors. We believed through the current study, the racial differences in drug responsibility can be clarified.
Blood sample 10cc
Study participant number: 35

All blood sample will be eliminated after study.
Who can used your blood sample? Dr. Chen Yueh Chung labotory; Graduate Institute of Medical Sciences, National Defense Medical Center, Taipei, Taiwan, ROC
Possible side effect: Physical: maybe mild ecchymosis. Psychological: none.
Any discomfort after blood sampling, please contact Dr. Chen.
Activity limitation: nil.
Other procedure:nil.

The personal lab. data after study will sent to you if needed.

CONFIDENTIALITY

Participant data will be kept confidential except in cases where the researcher is legally obligated to report specific incidents. These incidents include, but may not be limited to, incidents of abuse and suicide risk.

CONTACT INFORMATION

If you have questions at any time about this study, or you experience adverse effects as the result of participating in this study, you may contact the researcher whose contact information is provided on the first page. If you have questions regarding your rights as a research participant, or if problems arise which you do not feel you can discuss with the Primary Investigator, please contact the Institutional Review Board at 0227093600, ext. 3884.

VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. It is up to you to decide whether or not to take part in this study. If you decide to take part in this study, you will be asked to sign a consent form. After you sign the consent form, you are still free to withdraw at any time and without giving a reason. Withdrawing from this study will not affect the relationship you have, if any, with the researcher. If you withdraw from the study before data collection is completed, your data will be

returned to you or destroyed.

CONSENT

I have read and I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

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