Title: Efficacy of Immunoglobulin Plus Prednisolone in Reducing Coronary Artery Lesion in Patients with Kawasaki Disease

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For Subjects

Research name: Efficacy of Immunoglobulin Plus Prednisolone in Reducing Coronary Artery Lesion in Patients With Kawasaki Disease: A Multicentre Randomised Controlled Trial

Research number: 2018-142

Protocol version: 03, January 6, 2020

ICF version: 03, January 6, 2020

Research sponsoring institute: Children's Hospital of Fudan University

Research participating institute:

Principal investigators in research sponsoring institute (The physician in charge of the study): Guoying Huang, Fang Liu

Principal investigators in research participating institute (The physician in charge of the study):

Your child will be invited to participate in a clinical study. This informed consent gives you some information to help you decide whether to participate in this clinical study or not. Please read it carefully. If you have any questions, please ask the researchers responsible for the study.

Your child's participation in this study is voluntary. This study has been reviewed by the ethics review committee of the research institute.

Research purpose: about 10%~20% of patients with Kawasaki disease develop IVIG resistance, which contributes to the increased risk for coronary artery lesions. In the guideline released by American Heart Association in 2017, corticosteroids have been recommended as one of the initial treatment for the severe patients. The research aimed to access whether the addition of corticosteroid to the conventional initial treatment has superiority over the conventional IVIG plus aspirin treatment in efficacy and safety.

Research process: this is a multicentre, prospective, open-label, randomized controlled trial. The eligible patients with clear diagnosis of Kawasaki disease will accept the conventional IVIG plus aspirin or low dose of corticosteroid plus IVIG plus aspirin as the initial treatment in the acute phase. The study will compare the severity and incidence of coronary artery lesions, duration of fever, changes in laboratory data, and the Percentage of the need for additional treatment in two groups. The research is conducted by more than 10 regular children's hospitals with experience in diagnosing and treating KD. The study will last 1 year including the follow-up period, and follow-up for 4 times after hospital discharge is needed. (If you agree to participate in this study, we will communicate with you in detail and introduce related information about the study. Please provide information related to the disease, including course of disease, family history,

previous history, the results of tests your child has accepted and so on. We will number each subject and create a medical record file.)

Risk and discomfort: short-term treatment with the low dose of corticosteroids is widely used in the clinical practice, and there is no clear risk associated with the treatment.

Benefits: the treatment may reduce the incidence of coronary artery lesions. By studying your child's case, we will provide important and detailed advice on your child's treatment, long-term follow-up and disease management.

Privacy issue: if you decide to participate in this study, your child's personal data in and during the study are confidential. Physicians responsible for the research and other researchers will use your child's medical information for study. The information may include your child's name, address, phone number, medical history and information get from your child's visit. Your child's file will be kept in a locked filing cabinet for researchers only. To ensure that the study is conducted in accordance with the regulations, if necessary, members of the government management department or the ethics review committee may refer to your child's personal data in the research unit as required. When the results of this study are published, no information about you will be disclosed.

If your child is injured by participating in this study: you can receive free treatment and/or compensation if there is any harm associated with the clinical study.

You may choose not to participate in this study, or at any time inform the researcher to request withdrawal from the study. Your child's data will not be included in the study results, and any medical treatment and benefits will not be affected.

If your child need additional treatment, or if your child doesn't follow the study plan, or if your child has any injuries related to the study or for any other reason, the investigator may terminate your continued participation in the study.

You can keep track of the information and information related to this study and the progress of the study. If you have any questions related to this study, or if your child has any discomfort or injury during the study, or if you have any questions about the rights and interests of participants in this study, you can contact _____ by phone number: _____.

Informed Consent Form

I/We have read the informed consent form.

I/We have the opportunity to ask questions and all questions have been answered.

I/We understand that participation in this study is voluntary.

I/We can choose not to participate in this study, or quit at any time after informing the researcher without any discrimination or reprisals, and my medical treatment and rights will not be affected.

If my/our child needs other treatment, or if my/our child doesn't follow the study plan, or if there is any injury related to the study or if there is any other reason, the research physician may terminate my/our child involvement in this study.

I/We will receive a signed copy of the informed consent.

Patient's name: _____

Signature of patient: _____

Signature of parent or legal guardian:_____ relationship: _____

Phone number: _____

Date: _____

(Note: If the patient is under 10 years old and has certain understanding and expression skills, his legal guardian and the doctor should ask whether the child is willing to participate, and his legal guardian should sign the consent form. If the patient is over the age of 10, in addition to the signature of legal guardian, the patient also needs to sign in person.)

I (sign here) _____ agree that the researcher will use the biological samples and related data of my child again after deleting my and my child's personal information in the following study related to this subject.

Patient's name: _____

Signature of legal guardian:_____ relationship: _____

Date: _____

Research statement:

I have accurately informed the subject of this document that he/she has read this informed consent and has demonstrated that the subject has the opportunity to ask questions. I certify that he/she consented voluntarily.

Researcher's name:_____

Signature of researcher: _____

Date: _____