

RESEARCH DESCRIPTION

ABOUT STAMARIL (YELLOW FEVER VACCINE)



Name of the leading hospital

National Center for Global Health and Medicine

Name of the leading doctor

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WHAT IS CLINICAL RESEARCH?

Clinical research is a study of people to learn about certain diseases or to look for better treatments or prevention. This booklet gives you an explanation of the research you are introduced to. Please discuss with your family and decide whether you wish to take part in this research or not.

DO I HAVE TO JOIN IN?

We will explain about this research to you and your family. Please think with your family and decide if you wish to join in this research. It is absolutely okay if you do not want to join in. Even if you agree to join in, you can also quit if you changed your mind.

WHAT IS THE PURPOSE OF THIS RESEARCH?

If you chose to join in this research, we will inject you with a vaccine called STAMARIL and check if any adverse reaction would not happen. There is a risk of catching a disease called Yellow Fever in countries you are planning to visit. This disease does not exist in

Japan. If you receive a vaccine injection called STAMARIL, it could prevent you from contracting the disease.

EFFICACY AND ADVERSE REACTION

The vaccine could bring you a good change called “efficacy”. However, it could also bring you a bad change called “adverse reaction”.

If you noticed anything different than usual after the injection, please tell your family or your doctor.

 Good Change

You may be able to prevent Yellow Fever.

 Bad Change

You may lose your appetite, feel sleepy or get frustrated.

WHO WILL JOIN IN THIS RESEARCH?

To join in this research, you need to meet the following conditions.

You are chosen because you are likely to satisfy these conditions.

- 1) You are planning to go to the countries where you could contract Yellow Fever
- 2) You are older than 9 months old or an adult
- 3) The family of a child agrees with the participation
- 4) There are more other conditions not listed here

If you did not meet the necessary conditions, you might not be able to take part in this research. Your doctor will check you and decide if you meet the requirements.

RESEARCH METHOD

You will receive STAMARIL vaccine injection after your doctor checked you and decided that you meet the conditions. Your doctor will also make sure if you did not have any adverse effects. After you left the hospital, please watch out for yourself for about 30 days after the injection. If you notice anything different than usual, please tell your family and contact your doctor.

WILL ANYONE KNOW THAT I AM TAKING PART IN THIS RESEARCH?

Your doctor will not tell many people about it, without asking for your permission. However, your doctor will give information to other doctors who are also doing this research together. Even then, your doctor will not tell them the details, such as your address or your name.

WHEN DOES THE RESEARCH END?

Your doctors might stop conducting this research. For example, your doctor might decide not to give you the vaccine if you feel very sick before the injection. Your doctor will also decide not to give you the vaccine if you wish to quit taking part in this research.

WHO SHOULD I ASK IF I HAVE ANY QUESTION?

Please do not hesitate to ask any questions to your doctor if you have anything you do not understand or if you wish to discuss about this research.

Name of your doctor
Dr.
Name of your doctor's hospital (quarantine station)