

Fever study

Information Sheet

Greetings! I am _____ from the Christian Medical College Hospital. The following information sheet is provided to inform you about this study and your participation in it. A copy of this sheet will be provided to you. Kindly go through it carefully and feel free to ask any questions regarding this. You may ask questions at any time even after the start of the study. Your participation in this study is purely voluntary and you are free to withdraw from this at any point during the study. Also, you will not receive any incentive for answering questions or for being part of this study.

Purpose of the study-

We wish to find out through our study how the body reacts to two special types of typhoid fever called Scrub Typhus and spotted fever. You are selected for the study because you either have been a patient with scrub typhus or spotted fever at CMC, or you have been part of a study last year in this village. Scrub typhus is an infection that comes from the bite of a small insect. Spotted fever can come from the bite of a tick. Therefore these two diseases are sometimes called insect fever.

Methods-

We would like to do a blood test – similar to the blood tests we have done before in you. We will collect 5ml of blood from a blood vessel on your arm. The blood will be tested to see whether the body developed particles in your blood which may protect from another infection. Blood may be frozen and kept in a fridge for further testing for infectious illnesses in the future. The blood will not be shared with other institutions. It will only be used for research at CMC. In some cases, the investigator of this study, members of the Ethics Committee or the regulatory authorities may look at your health records held at CMC.

Approximate duration of this study-

For you the study will only happen today and will last for about 15 minutes. You don't need to do anything after that.

Description of the discomforts, inconveniences, risk factors that can be reasonably expected as a result of participation in this study-

The questions that will be asked may not cause any discomfort to you as they are focused only on assessing the details of your previous hospitalization. The blood test is a simple blood test as we usually do it at our clinics. This does not cause health problems but sometimes can cause mild pain that will not last for long.

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Unforeseeable risk-

There are no such risks expected during this study.

Compensation in view of study related injury-

There is no study related injury expected from this study.

Anticipated benefits from this study-

While this study has no benefit for you today, we will let you know the result of the blood test. Further, other people in your village may benefit if we know how common scrub typhus is. Doctors may be able to do more for this disease here.

Circumstances under which the principal investigator may withdraw you from the study participation-

If you wish not to answer questions or do not want us to contact or meet you regarding this particular study, you will be withdrawn from the study. If you withdraw, this will not stop the medical care provided to you and your family. We will use the information you have provided until then for our research study, but will not contact you again for further information.

What happens if you choose to withdraw from the study participation-

You can choose at any time to withdraw from the study. There will be no disadvantage for you.

Confidentiality-

Your identity will not be revealed to anyone else. Your name and address will not appear in any research article.