Clinical Trial Protocol	
Protocol Title	Testing of Identification Markers for strokE
Acronym	TIME
NCT Identification Number	Not yet assigned
Version	2.0
Version date	21st January 2020
Study Sponsor	POCKiT diagnostics Ltd, Future Business Centre, CB4 2HY Cambridge, United Kingdom
Sponsor's Head of Clinical	Edoardo Gaude, PhD, POCKiT diagnostics Ltd

The University of Mississippi Medical Center
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CONSENT FOR STORAGE AND FUTURE USE OF SAMPLES

Study Title: Testing of Identification Markers for stroke (TIME)
Sponsor: POCKiT Diagnostics
Principal Investigator: Shashank Shekhar MD
Performance Site: University of Mississippi Medical Center

Introduction

You are being invited to be in this observational research study because you were admitted to the Emergency Department with a suspected diagnosis of stroke. Please ask us about anything in this document or that we tell you that you do not understand.

Purpose

We are doing this study to find new ways to diagnose stroke outside the hospital. This could be done by measuring certain blood molecules in patients right after they had a stroke. Early diagnosis is important in helping physicians provide the best possible treatment options. We will collect blood samples from patients with a suspected stroke. We will then measure the levels of certain blood molecules to understand if these can show the difference between people who had different types of stroke.

Procedures

If you agree to participate in this study, you will provide a teaspoon of blood in addition to the blood drawn by the Emergency Department.

We would like to keep and store left over samples of your blood to use in future research studies. The samples may be used for commercial purposes.

We may use the samples to help us:

- Learn more about your disease.
- Learn more about other diseases or conditions.
- Find new ways to help people feel better.
- Learn how to treat, cure, or prevent the occurrence of stroke.

Risks

There is very minimal risk to patients who participate. The risks of getting blood drawn include pain, bruising, or minor infection.

Benefits

You will not receive a direct benefit from being in this research study. We hope to learn information that may help others in the future.

Compensation

You will not be paid for participating in this study.

Voluntary Participation

Your participation is voluntary. If you decide not to participate in this study you will not suffer a penalty or loss of benefits to which you are otherwise entitled.

Withdrawal

You may choose to stop your participation in this study at any time. If you decide to withdraw the information already collected about you may still be used in this study but additional information will not be collected. Your decision to stop your participation will have no effect on the quality of medical care you receive at the University of Mississippi Medical Center.

Confidentiality

Every effort will be made to keep the information we learn about you private. Study personnel, the Food and Drug Administration (FDA), the Office for Human Research Protections and University of Mississippi Medical Center's Institutional Review Board (IRB) and Office of Integrity and Compliance may review the study records. Any information which accompanies the sample when it leaves the hospital will have your name, address, and any other possible identifiable information removed so that you cannot be recognized from it.

Protected Health Information

Protected health information is any personal health information through which you can be identified. The information collected in this study includes: your final diagnosis, demographics, clinical data, and stroke scaling scores. By signing this consent document, you authorize Dr. Shekhar and his study staff to collect this information and use your records as necessary for this study.

Number of Participants

We expect 1,000 participants to enroll in this study here and 2,000 nationwide and internationally.

Questions

If you have any questions about this study, please call Dr. Shekhar at 601-984-5500.

You will be given a copy of this consent document for your records if you agree to participate in this study.

Statement of Participation

Your samples and some information about you will be stored in the UMMC Biobank and POCKiT Diagnostics. The samples and information may be used by other researchers, but no identifiers will be shared and no effort will be made to reconnect or re-identify your samples.

It is your choice. You do not have to let us do this and there will be no penalty if you do not let us keep the left over samples. This part of the study is optional and you can be in the study no matter what you decide.

_____ You may take, store and use samples of my blood for future research studies related to my condition.

_____ You may take, store and use samples of my blood for future research studies. The studies do not have to be related to my condition.

I have been told about this study and the possible risks and benefits. My participation is voluntary and I may withdraw at any time without any penalty or loss of benefits to which I am entitled, including medical care at the University of Mississippi Medical Center.

By signing this form I am not giving up any legal rights I may have.

_____
Printed name of Participant

_____ _____
Signature of Participant Date

_____
Printed name of person obtaining consent

_____
Signature of person obtaining consent

_____
Date

I acknowledge that the participant identified above has been entered into this study, with properly obtained informed consent.

_____

Signature of Principal Investigator

_____

Date