Patient Information and Consent Form (Non-Interventional Study)

Study title: *„Development and validation of a highly sensitive molecular multiplex assay for Plasmodium species detection“ (MolMal)*

Studienteilnehmer-ID
(vergeben durch das Studienzentrum)

Study center:
Eberhard Karls University of Tübingen, University Hospital Tübingen, Institute of Tropical Medicine, Travel Medicine, and Human Parasitology, Wilhelmstr. 27, D-72074 Tübingen, Germany

Principle Investigator:
Prof. Dr. med. Sabine Bélard, University Hospital Tübingen, Institute of Tropical Medicine, Travel Medicine, and Human Parasitology, Wilhelmstr. 27, 72074 Tübingen, Germany. Phone: +49 7071 29-85445; Email: sabine.belard@med.uni-tuebingen.de

Patient Information

Dear Patient,

Malaria is an infectious disease caused by various species of Plasmodium parasites and is transmitted through the bite of an Anopheles mosquito. Malaria can cause symptoms such as headaches, fever, and anaemia, and if left untreated, can become life-threatening or even fatal. The severity and treatment of malaria also depends on the species of the parasite. Rapid diagnosis and treatment are crucial for a swift recovery.

Malaria occurs worldwide in tropical and subtropical regions, particularly in African, South American, and Asian countries. Isolated cases of infections from imported mosquitoes have also been reported in some Southern European countries and near airports.

Since your doctor suspects or wishes to rule out a malaria infection based on your symptoms and travel history, or wants to monitor the response to malaria therapy, we would like to invite you to participate in our study.

What is the purpose of the study?

We are conducting a scientific study to develop a molecular test (Multiplex PCR) for malaria that improves diagnosis. This PCR test is more sensitive than conventional methods (thick blood smear or rapid test), meaning it can detect the presence of parasites even if they are present in very low numbers in the blood. Additionally, the PCR test allows for the precise identification of the parasite species, which enables more targeted treatment. We aim to validate the new PCR test using blood samples from individuals undergoing conventional malaria diagnostics, with the goal of eventually incorporating it into routine diagnostics.

What data will be collected?

In addition to the PCR test result, we will also collect the results of the standard malaria diagnostics performed at the Institute of Tropical Medicine at the University Hospital Tübingen or the hospital where you are being treated. We would also like to know which countries you have travelled to. This information helps us better understand the risks of imported malaria. Your data will be processed in a pseudonymized manner, and no personal data will be collected.

Are there any risks associated with participation?

Participation in the study poses no additional risks to you. We only require the remnants of your blood sample; no additional blood draw is needed for the PCR test. The blood draw for conventional malaria tests will be carried out whether or not you participate in the study.

What are the benefits of participating?

You will receive an additional laboratory test that may assist you and your doctor in diagnosing or ruling out a malaria infection and could allow for more targeted therapy.

How can I find out the PCR test result?

Upon request, we will gladly provide you with the test result. In the case of an abnormal result that is relevant to your further treatment, we will, of course, pass it on to your treating physician.

Who is conducting the study?

The study is being conducted and led by Prof. Dr. Sabine Bélard, Dr. Albert Lalremruata, and Ms. Hannah Sondermann, along with their study team.

If you have any questions about this study, please contact:

Name: Hannah Sondermann
Address: Institute of Tropical Medicine, Wilhelmstraße 27, 72074 Tübingen
Email: hannah.sondermann@med.uni-tuebingen.de

OR:

Study Office of the Institute of Tropical Medicine
Address: Institute of Tropical Medicine, Wilhelmstraße 27, 72074 Tübingen
Phone: +49 7071 29 75931
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Email: studien.itm@klinikum.uni-tuebingen.de

We thank you in advance for your participation and support of our research.

Declaration of consent to study participation

Studienteilnehmer-ID
(vergeben durch das Studienzentrum)

Study title:
"Development and validation of a highly sensitive molecular multiplex assay for Plasmodium species detection" (MolMal)

☐ I have read the patient information for the study, or it has been read to me. I have had the opportunity to ask questions, and all of my questions have been answered. I have been informed about the objectives and procedures of the study and have understood them.

☐ I know that I can withdraw my voluntary participation at any time without any disadvantages to me.

☐ I consent to participate in this study.

☐ I have received a copy of the information sheet and the consent form. A copy will remain at the study site.

Signature of the Participant:

_____	_____	_____
(Surname and First Name in Block letters)	(Place, Date)	(Signature)

For Minors, Signature of Legal Guardian:

Child´s Name: _____

_____	_____	_____
(Surname and First Name in Block letters)	(Place, Date)	(Signature)

Statement and Signature of the Person Providing Information:

_____	_____	_____
(Surname and First Name in Block letters)	(Place, Date)	(Signature)

Declaration of Consent to the Handling of the Data Collected in the Study

Studienteilnehmer-ID (vergeben durch das Studienzentrum)

☐I consent to the use of the data collected in this study in the manner described above. I understand that my data will be stored in a pseudonymized form and will not be shared with third parties. I know that I can request the deletion of my data at any time.

☐I am aware that the results of this study may be published in medical journals, but in an anonymized form, so that no direct reference to me can be made

Signature of the Participant:

(Surname and First Name in Block letters)	(Place, Date)	(Signature)

For Minors, Signature of Legal Guardian:

Child´s Name: _____

(Surname and First Name in Block letters)	(Place, Date)	(Signature)

Information and Consent Form on Data Protection

Information on Handling Data Collected in the Study:

In the course of the study ("Development and Validation of a Highly Sensitive Molecular Multiplex Assay for Plasmodium Species Detection"), your personal data[1] will be collected and processed.

The documentation and archiving of your data will be pseudonymized[2] in a secure electronic database, accessible only to authorized staff, including doctoral students who are bound by professional and data confidentiality. To verify the correct transfer of treatment data from your medical record into the encrypted study database, authorized persons may review personal medical data related to the study. All involved staff are subject to confidentiality obligations.

The legal basis for the processing is Article 6(1)(a) and Article 9(2)(a) of the General Data Protection Regulation (GDPR) in conjunction with your consent. Your explicit consent, by signing the data protection consent form, is required for the collection, storage, use, and transfer of your data.
The research results from the study will be published in anonymized form in scientific journals or databases. The pseudonymized data will be processed on collection forms and electronic storage media.

Data will be retained for 10 years after the study's conclusion or termination. They are protected against unauthorized access and will be deleted once they are no longer needed for the study's data processing purposes, or at the latest after 10 years.

The information obtained in this study will be processed exclusively within the EU, the European Economic Area, or in countries with comparable data protection standards.

You can withdraw your consent at any time, either in writing or orally, without providing reasons, and without suffering any disadvantages. If you withdraw your consent, no further data will be collected. However, data processing that occurred before the withdrawal will remain lawful.

You can also request information about your stored data at any time, as well as request a free copy, and have the right to correct inaccurate data. You may also request at any time that your data be deleted or anonymized so that no reference to you can be made.

These rights are limited under § 13 of the State Data Protection Act (LDSG) to the extent that exercising these rights would likely render the realization of the respective research purposes impossible or seriously impaired and the restriction is necessary for fulfilling the respective research purposes. The right to information does not apply if the data are required for scientific research and providing information would involve disproportionate effort.

The entity responsible for data processing under Article 4(7) GDPR is the University Hospital Tübingen, a legally competent institution under public law at the University of Tübingen, Geissweg 3, 72076 Tübingen, Tel.: +49 7071 29-0, service@med.uni-tuebingen.de. The person responsible for data processing in this study is the study leader, Prof. Sabine Bélard (Email: sabine.belard@med.uni-tuebingen.de, Phone: +49 7071 29-82365). If you have any questions about the use or processing of your data, please contact her.

If you have concerns or complaints regarding data protection or wish to exercise your rights under Articles 15ff. GDPR, you may contact the following: University Hospital Tübingen, Data Protection Officer, Geissweg 3, 72076 Tübingen, Tel.: +49 7071 29-87667, Email: Datenschutz@med.uni-tuebingen.de. You also have the right to lodge a complaint with the relevant supervisory authority for data protection (State Commissioner for Data Protection and Freedom of Information in Baden-Württemberg, Postfach 10 29 32, 70025 Stuttgart, Tel.: +49 711 / 61 55 41 - 716, Email: Poststelle@lfdi.bwl.de).

[1] **Personal Data:** Name, country of travel, results of study-related examinations.
[2] **Pseudonymized** means that your personal data is encrypted and can only be associated with you by using an identification list, which is accessible exclusively to authorized study personnel bound by confidentiality obligations.

Declaration of Consent to the Handling of the Data Collected in the Study

I hereby declare that I agree with the collection and processing of data within the framework of this study and their encrypted (pseudonymized) transmission.
I consent to authorized persons reviewing my personal medical records for data verification purposes and release the treating physician from their professional confidentiality obligation to that extent.
I am aware that the results of this study may be published in medical journals, but in anonymized form, so that no direct reference to me can be made.
I have been informed that I can request information about my stored data and the correction of inaccurate data at any time.
I understand that I can request the deletion or immediate anonymization of my data at any time, such as upon withdrawal from the study.
I declare that I have been adequately informed about the collection and processing of my data in this study and my rights.
I agree to the use of the data collected in this study as described above. For the review by authorized persons, I release my treating physicians and the study team from their confidentiality obligations to the extent necessary.

I expressly agree that the study team may contact me after the study concludes to ask whether I consent to the data collected in the study being used and processed for specific future research projects by the clinic or institute.
Yes □ No □

□I declare that I have been adequately informed about the collection and processing of my data in this study and my rights.

Signature of the Participant:

_____	_____	_____
(Surname and First Name in Block letters)	(Place, Date)	(Signature)

For Minors, Signature of Legal Guardian:

Child´s Name: _____

_____	_____	_____
(Surname and First Name in Block letters)	(Place, Date)	(Signature)