

Content and Aim of the Study:

In this scientific study, we want to investigate the changes in microvascular structure and function in the skin and muscles of patients with type 2 diabetes mellitus using two novel optoacoustic imaging methods (RSOM and MSOT).

Measurements are taken with our devices (similar to an ultrasound examination) on the lower leg and forearm (approx. 18 minutes in total).

A blood sample will also be taken for laboratory chemical, molecular and genetic analysis.

In addition, a urine sample will be collected.

The aim of our study is to correlate the clinical RSOM and MSOT measurements with the data from the molecular and genetic analysis of the blood and urine samples. The aim is to develop better diagnostic methods for diabetes and possible secondary complications.

For the RSOM and MSOT imaging methods, your arm and leg are illuminated at various points with safe laser light and tiny sound waves from the skin and muscle layers are measured by our devices using ultrasound sensors. Protective goggles will be worn.

The study involves 800 participants at Klinikum rechts der Isar and 400 participants at the University of Tartu in Estonia.

In preparation, we ask you to refrain from the following:

- at least 48 hours before the measurements: exercise,
- the day before: consumption of alcohol, coffee and fatty foods,
- at least 9 hours before the planned measurements: consumption of food other than water,
- on the day of the measurement: smoking,
- in the morning before the measurement, if possible: take your regular medication.

We therefore ask you to bring your own breakfast. You can then eat it after the examination.

We ask you to provide truthful information in the questionnaire so that the study can be successful.

Your participation in the study includes two appointments at intervals of about 24 months.

Procedure of the Study:

Participation in the study is subject to following:

Inclusion Criteria:

Age: 40-90 years old and all gender

Group A: Patients with diagnosed diabetes mellitus type 2 without vascular complications.

Group B: Patients with diagnosed diabetes mellitus type 2 with at least one microvascular complication (e.g. neuropathy, nephropathy and retinopathy) without macrovascular complications.

Group C: Patients with diagnosed type 2 diabetes mellitus with microvascular complications and at least one macrovascular complication (e.g. coronary heart disease, carotid atherosclerosis, peripheral arterial occlusive disease).

Group D: Healthy subjects (reference group).

Exclusion Criteria:

Age under 40 or over 80 years.

Pregnancy or breastfeeding.

Heavily pigmented skin (leads to a strong attenuation of the RSOM signal due to the presence of melanin in the skin).

Documented or suspected light allergy, light intolerance, contact dermatitis and particularly sensitive skin or dermatological diseases (e.g. psoriasis).

Open or infected wounds at the measuring points.

Duration of Examination:

Two examination appointments at intervals of 24 months. One examination appointment will last approx. 60 minutes.

Place of Examination:

Outpatient clinic of the Clinic and Polyclinic for Vascular and Endovascular Surgery of the Klinikum rechts der Isar.

Contact Information

Study Coordination and Medical Lead:

Dr.rer.nat. Angelos Karlas

Tenure Track Gruppen leader – Clinical Bioengineering Group

Chair of Biological Imaging

Resident - Vascular and Endovascular Surgery

Klinikum rechts der Isar

Klinikum rechts der Isar Technical University of Munich

(TUM) Einsteinstraße 25 (TranslaTUM)

81675 Munich

Tel. 089/4140-9303

E-mail: angelos.karlas@tum.de

Public Transportation:

Haltestelle Max-Weber-Platz U4 / U5

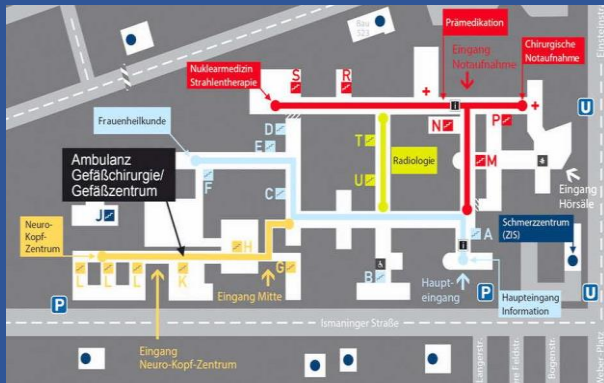
Straßenbahn Line 15 / 16 / 19 / 25

Bus 190 / 191

Place of Examination:

Vascular surgery outpatient clinic, entrance Neuro-Kopf

Zentrum in Ismaninger Straße (see map)



Klinikum rechts der Isar
Technische Universität München

Do you have type-2 diabetes mellitus?

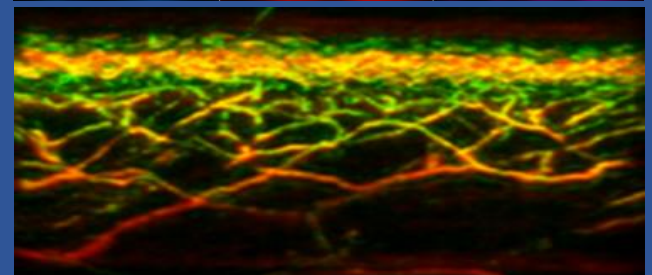
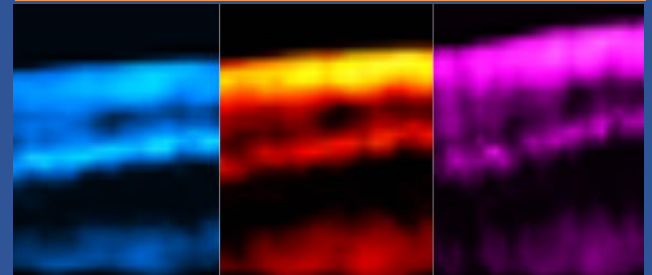
Would you like to take part in our study?

We are also looking for healthy volunteers.

Conduct research with us! We are investigating changes in the skin and muscles in type-2 diabetes mellitus.

OPTOMICS Study

Combining optoacoustic imaging phenotypes and multi-omics to advance diabetes healthcare



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