Project title:

Pilot study: Influence of ischemic preconditioning on the orthostatic competence of the microcirculation in the lower extremity

Date: 20.07.2023

1) Studyprotocol

Procedures for informing and obtaining consent:

The recruited subjects will be informed about the nature, importance, risks and scope of the intended scientific investigation in a personal interview with one of the investigators and will receive patient information. After sufficient time for reflection, the consent will be confirmed in writing on the form prepared for this purpose - declaration of consent.

Measures:

The experimental setup consists of two separate measurements. In the first measurement, the subject is ortho-statically stressed by changing the position (lying to upright) on a tilting table (similar to the established tilting table test). 24 hours after the first measurement, the ischemic preconditioning will be carried out in three cycles with a directly subsequent tilting table test.

1. Tilting table

Time (min)	0-15	15-30	30-45	24 h Break
Position	lying	upright	lying	

Ischemic preconditioning and 2. Tiliting table

Time (min)	0-10	10-20	20-30	30-40	40-50	50-60	60-75	75-90	90-105	30-45
Procederes		Ischemia	Reperfusion	Ischemia	Reperfusion	Ischemia				
Position	*lying*								upright	lyring

The measurements are carried out in a room with a constant temperature of 21° without a window. The test subjects should not do any sport or drink alcohol for 24 hours beforehand and not drink coffee for 6 hours beforehand.

The respective tilting table measurements are carried out in the same way: The subject is laid down on the tilting table (standing board 20.200, RFH-Rehatechnik GmbH, Bayreuth, Germany). The fixation of the 3 mm probe (O2C® Laser Doppler and tissue spectrometry LEA Medizintechnik GmbH, Giessen, Germany) for measuring the microcirculation is sticked of on the antero-lateral thigh (potential donor area of an ALT flap) in a standardized manner with transparent plaster (CURAPOR® cannulas Fixation plaster i.v.). A non-invasive, continuous blood pressure measurement on the left arm and ring finger (Finapres® NOVA, Finapres Medical Systems BV, Enschede, Netherlands) is used for precise circulatory monitoring. The subject is fixed to the tilting table with belts. During the entire measurement, the subject is asked to lie relaxed and not to make any active movements.

After 15 minutes, the tilting table or the subject on the tilting table is tilted fully automatically (electrically) from a horizontal (0°) to an upright (80°) position. The subject remains in this position for 15 minutes. Then the tilting table or subject on the tilting table is tilted fully automatically (electrically) again from the upright (80°) to a horizontal (0°) position or position. The subject remains lying down (starting position) for further 15 minutes. The first measurement is then ended.

The second measurement with previous ischemic preconditioning is carried out under identical conditions. Positioning the patient on the tilting table and attaching the monitor is identical to the first measurement. The empty tourniquet (VBM Tourniquet Touch®, Sulz a.N. Germany) is attached to the right upper arm. The measurement starts from this point in time. After lying flat for 10 minutes, the upper arm tourniquet is inflated to 250mmHg. In all subjects, the ischemia was verified by palpation and Doppler signal of the radial artery. The ischemia phase is carried out for 10 minutes, so the tourniquet is opened, and a 10-minute reperfusion phase is started, followed by a total of 3 cycles. After the 3rd ischemia phase, the tilting table test – as described above – followed with a 15-minute lying interval.

2) Statistical Analysis Plan

Since there will be non-normal distribution and little data, we will use non-parametric tests. The Wilcoxon test compares the values of dependent samples (pre and post). If the p-value (level of significance) is < 0.05, then it would be significant and there would be differences between the pre and post values. If the p-value (level of significance) > 0.05, then it would not be significant and there would be no differences between the pre and post values.