Aim of the Project

The INTERFAST cohort study with embedded pilot randomized control trial aims to investigate the effects of repeating fasting periods on human physiology, aging process and molecular cellular processes in humans. We will be able to study long term effects (subjects in the cohort study, who already practise ADF for a defined time period) and short term effects (subjects randomized to the ADF group) of this nutritional intervention.

Inclusion / Exclusion criteria

Inclusion criteria:

- Age between 35 and 65 years
- Body mass index in the range of 22.0 – 30.0 kg/m^2
- Fasting blood glucose <110mg/dL (without medication)
- LDL-cholesterol <180 mg/dL (without medication)
- Blood pressure <140/90 mmHg (without medication)
- Stable weight (change <± 10%) for 3 months immediately prior to the study

Exclusion criteria:

- No history of metabolic disorders or cardiovascular disease
- No acute or chronic inflammatory disorder
- No current medications to regulate blood sugar, blood pressure or lipids or hormones
- No heavy drinking (more than 15 drinks/week)
- No use of tobacco or recreational drugs within past 5 years
- No dietary restrictions (e.g. vegetarianism and vegan)
- Known Malignancy
- Women who are pregnant, breast-feeding or trying to become pregnant
- History of any chronic disease process that could interfere with interpretation of study results
- Women or men on hormonal supplementation or anti-conceptive hormonal medication for at least 2 months
- Therapy with antidepressants within past 6 months
- Regular therapy with acetylsalicylic acid

Dataset / Parameters

Cohort (Alternate day fasting for at least 6 months before the start of the trial – 30 subjects) as well as RCT (60 subjects – randomized to either intervention group (alternate day fasting) or control group with no intervention 1:1).

The following study procedures will be done:

- Demographics
- Medical History
- Concomitant medication
- Vital signs
- Physical examination
- Blood sampling with orale glucose tolerance test (oGTT)
- Electrocardiography (ECG)

- Continuous Glucose monitoring (CGM)
- Accelerometer (Movisens®)
- Buccal mucosa sampling
- 24h blood pressure measurement
- Sputum sampling
- Faeces sampling
- Echocardiography
- Dual-energy X-ray absorptiometry (DXA)
- Questionnaires (FFQ, Physical Activity)
- Retinal vessels analyser
- Hand-Grip Test
- Endothelial function (EndoPat 2000)
- Intima media thickness (IMT)
- Pulse wave analysis
- Resting energy expenditure (REE)
- Bioelectrical impedance analysis (BIA)
- Dry eye assessment (optional)
- Flow mediated dilatation (FMD)

Samples / Material

Starting in May 2018, samples from 90 subjects were collected. The biobank specimen comprises EDTA-Plasma, Serum and Urine which are stored at -80°C.

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