Trial Registration Data Set

Data category	Information
Primary registry and trial identifying number	German Clinical Trials Register DRKS00021784
Date of registration in primary registry	24 September, 2020
Secondary identifying numbers	Universal Trial Number (UTN): U1111-1258-5317
Source(s) of monetary or material support	University Hospital of Halle (Saale), Germany
Primary sponsor	University Hospital of Halle (Saale), Germany
Secondary sponsor(s)	German Heart Research Foundation
Contact for public queries	Dr. Jochen Dutzmann, +49(0)345/557-2457
Contact for scientific queries	Dr. Jochen Dutzmann University Hospital of Halle (Saale), Germany
Public title	Intermittent fasting after ST-elevation myocardial infarction to improve left ventricular function
Scientific title	Intermittent fasting after ST-elevation myocardial infarction to improve left ventricular function (INTERFAST-MI): a pilot randomized controlled trial
Countries of recruitment	Germany
Health condition(s) or problem(s) studied	ST-elevation myocardial infarction
Intervention(s)	Intermittent Fasting (time-restricted feeding; at least 16 hours fasting, not more than 8 hours unrestricted diet) for three months; then voluntary continuation of intermittent fasting or cross-over for three more months
	Control (no specific dietary restrictions) for three months, the voluntary cross-over or three more months
Key inclusion and exclusion criteria	Ages eligible for study: ≥18 years Sexes eligible for study: both Accepts healthy volunteers: no
	Inclusion criteria: written informed consent, ST-elevation myocardial infarction (or equivalent)

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	Exclusion criteria: missing informed consent, participation in other clinical trials, patients with cardiac devices not approved for MRI scanning, kidney failure (GFR <30 ml/min), claustrophobia, antidiabetic therapy with sulfonylurea, pregnancy, employees of the study center
Study type	Interventional
	Allocation: randomized intervention model. Parallel assignment masking: no masking
	Primary purpose: prevention
	Pilot
Date of first enrolment	November 2020
Target sample size	48
Recruitment status	Recruiting
Primary outcome(s)	Left ventricular myocardial function at four weeks after randomization (evaluated by echocardiography)
Key secondary outcomes	- all-cause hospitalization - hospitalization from cardiovascular cause - all-cause death - death from cardiovascular cause - myocardial infarction - revascularisation - stroke - patient weight - blood pressure - medication - comorbidities - left ventricular function at three and six months after randomization - further characterization of myocardial function evaluated by echocardiography (i.e. Kinetikstörungen, LVEDP, E/e‘) - myocardial scar and edema (evaluated by cardiac MRI) - clinical chemistry and hematology (hGH, adiponectine, NT-proBNP, creatinine, fasting insulin, fasting blood glucose, HbA1c, blood count, IL-1, IL-6, C-reactive protein, homocysteine, cholesterine, LDL, HDL, triglycerides) - Peripheral Blood Mononuclear Cells

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	- DNA-Methylation of circulating cells („epigenetic clock“) Follow-up: 6 months. Study visits at regular ambulatory visits at 4 weeks, 3 months, and 6 months