EMMY

Aim of the Project

The aim of this mechanistic study is to investigate the impact of Empagliflozin on cardiac function and biomarkers for heart failure in patients with acute myocardial infarction. Since previous trials in acute myocardial infarction using aldosterone blockers demonstrated that an early intervention might be crucial for a beneficial outcome, the study team have chosen to start treatment within 72 hours after performance of a coronary angiography for acute myocardial infarction.

Inclusion / Exclusion criteria

The national, randomized, prospective, placebo-controlled, double blind, multicenter study includes patients with myocardial infarction with evidence of significant myocardial necrosis defined as a rise in creatinkinase >800 U/l and a troponin T- or I level >10x ULN. In addition, at least 1 of the following criteria must be met:

- Symptoms of ischemia
- ECG changes indicative of new ischemia (new ST-T changes or new LBBB)
- Imaging evidence of new regional wall motion abnormality

Patients were aged from 18 to 80 years, with a eGFR >45 ml/min/1.73 m^2, a blood pressure >110/70 mmHg and give their written informed consent, according to the Declaration of Helsinki and national regulations. Patients with any other form of diabetes mellitus than type 2 diabetes mellitus or history of diabetic ketoacidosis are excluded. Further exclusion criteria are a blood ph<7.32 or haemodynamic instability as defined by intravenous administration of catecholamine, calciumsensitizers or phosphodiesterase inhibitors.

Dataset / Parameters

The following patient characteristics will be collected at study inclusion, 6 weeks and 26 weeks after randomization: vital signs, body weight, physical examination, cardiac ultrasound, blood samples (including nt-proBNP, liver function parameters, renal function parameters and biobank samples. In a smaller subcohort, urine samples will be collected in addition.

This study will capture and process data using an electronic Case Report Form (Clincase) which is a fully validated high quality electronic data capture system, which has a full audit trail and controlled level of access.

The following study procedures will be done:

- Demographics
- Medical History
- Concomitant medication
- Vital signs
- Physical examination
- Electrocardiography (ECG)
- Echocardiography

Samples / Material

Starting in May 2017, samples from 476 subjects are collected. The Biobank specimen comprises Plasma, Serum, Whole blood, Na-Citrat and Urine, stored at -80°C.

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endocrinology diabetology

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EMpagliflozin bei Patienten mit akutem MYokardinfarkt
Prospektive, randomisierte multizentrische Phase III Studie