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Rationale and design of the TETHYS trial: the effects of methotrexate therapy on myocardial infarction with ST-segment elevation.

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Abstract

INTRODUCTION: Methotrexate is a drug that has shown anti-ischemic effects in animal studies and positive results in heart failure clinical trials.

METHODS: We will randomly assign 80 patients with acute myocardial infarction to receive methotrexate (0.05 mg/kg bolus followed by 0.05 mg/kg/h for 6 h) or matching placebo. The primary outcome will be the area under the curve (AUC) for creatine kinase (CK) release for 72 h. Secondary outcomes will be the peak levels of CK, CK-MB fraction and troponin I, AUC for CK-MB and troponin I, levels of B-type natriuretic peptide (BNP), high-sensitivity C-reactive protein (hsCRP) and erythrocyte sedimentation rate (ESR) at admission and at 30 days, left ventricular ejection fraction (LVEF) at baseline and at 30 days, death, TIMI (thrombolysis in myocardial infarction) frame count in the culprit artery, Killip score after 72 h and rate of reinfarction at 30 days.

RESULTS: We expect a reduction in the AUC for CK, CK-MB and troponin release in the methotrexate group compared to the placebo group. We also expect a reduction in the levels of BNP, hsCRP and ESR and an improvement of LVEF and TIMI frame count in the methotrexate group.

CONCLUSION: This trial may be the first to demonstrate the anti-inflammatory and anti-ischemic effects of methotrexate in patients with acute myocardial infarction.

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