Abstract: New possibilities of thrombolytic therapy in patients with STEMI according to a multicenter clinical study FRIDOM1.

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Aim: to assess the efficacy and safety of the single bolus of a new Russian genetically engineered drug Fortelyzin® in comparison with the single bolus of drug Metalyse® in ST-segment elevation myocardial infarction patients with 12 hours after symptoms onset.

Materials and methods: Clinical trial took place from 2014 to 2016 in 11 clinical centers in Russia, the study was planned as a non-inferiority study with an assessment of the main results of intention to treat. The study included 382 STEMI patients, who were randomized to the Fortelyzin® and Metalyse® groups. Fortelyzin® was administered by bolus at a dose of 15 mg regardless of body weight, Metalyse® was administered by bolus at a dose of 30-50 mg depending on body weight. Thrombolytic therapy was accompanied by anticoagulant, double antiplatelet therapy in standard dosages with subsequent planned or emergency percutaneous coronary intervention (PCI). The observation was carried out within 30 days from the moment of randomization.

Results: the reperfusion according to 90 min ECG data occurred in 80% and according to coronary angiographic data (TIMI 2 + TIMI 3) in 70%. The "no less effective" rating, conducted by the difference in the CAG criterion (TIMI 2 + TIMI 3) in the Fortelyzin® and Metalyse® groups, was equal to 0.81% and did not go beyond the limit of the clinical significance of 12.5. The primary final combined point which includes the sum of deaths from any causes + repeated myocardial infarction + cardiogenic shock, in the Fortelyzin® and Metalyse® groups was 12.63% and 12.56% (p>0.99), respectively. In a clinical study, no intracranial hemorrhage was observed in both groups. In the Fortelyzin® and Metalyse® groups, one patient was observed with large bleeding according to TIMI and GUSTO classification. Minor bleeding was observed in the Fortelyzin® group - 3.7%, in the Metalysis® group - 10.5% (p = 0.02).

Conclusion: in the clinical trial FRIDOM1, it was demonstrated that a single bolus administration of Fortelyzin® at a dose of 15 mg in combination with anticoagulant and double antiaggregant therapy followed by PCI, is no less effective and safe than the use of Metalyse®.

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