OBSERVATIONAL STUDY

Clinical and Economic Outcomes of hs-cTns for diagnosis of NSTEMI in Patients With Chest Pain in EDs in Italy-An Observational Study - TROCAR 2017

No Profit Study: ***TROCAR 2017***

Promoter
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SUMMARY

This multicenter observational study is a clinical, organizational and economic evaluation of the different quantitative assays of high-sensitivity cardiac troponin in patients with suspected acute myocardial infarction and non-ST-elevation ECG (NSTEMI) at admission at 12 Italian Emergency Departments.

This document provides a synopsis of the Study Protocol (original in Italian)

SYNOPSIS

Title	***Clinical and Economic Outcomes of hs-cTns for diagnosis of NSTEMI in Patients With Chest Pain in EDs in Italy-An Observational Study TROCAR 2017***
Promoter	National Institute of Health National Health Technology Assessment Centre
Type of study	No profit with in vitro diagnostic medical devices routinely employed in clinical practice
Clinical phase	Post marketing
Background	Myocardial infarction is one of the leading causes of death and disability worldwide. In addition to standard diagnostic methods, it has been shown that high-sensitivity cardiac troponin assays allow greater sensitivity in the diagnosis of myocardial infarction and assume a central role for both exclusion ("rule out") and confirmation ("rule in") of acute myocardial infarction, while allowing to reduce the time interval between Emergency Department admission and presumptive diagnosis. Considering the relevance of this topic, we propose to conduct an observational study in real world clinical practice settings at Emergency Departments, aiming to evaluate clinical and economic aspects deriving from the use of the different quantitative assays of high-sensitivity cardiac troponin currently available in patients with suspected acute myocardial infarction and non-ST-elevation ECG (No ST elevation myocardial infarction - NSTEMI) at admission, including time of diagnosis and number of laboratory and imaging tests performed.
Study design	Observational
Objective	Clinical, organizational and economic evaluation of the different quantitative assays of high-sensitivity cardiac troponin in patients with suspected acute myocardial infarction and non-ST-elevation ECG (NSTEMI) at admission at the Emergency Department

Primary Endpoint	Time to diagnosis at the Emergency Department
Secondary Endpoints	% rule in patients (NSTEMI diagnosis) % rule out patients (exclusion of NSTEMI) % patients dead 30 days after Emergency Department admission % patients with myocardial infarction 30 days after Emergency Department admission % patients with major adverse events 30 days after ED admission
Pharmacoeconomic endpoint	Number and cost of laboratory and imaging tests performed at the Emergency Department
Evaluation of effectiveness	Outcome measures: time of diagnosis, death or myocardial infarction 30 days after Emergency Department admission. Sensitivity and Negative Predictive Value of myocardial Infarction ("rule out") with different quantitative assays of high-sensitivity cardiac troponin, according to the standard operating protocols of the participating Centers. Sensitivity and Negative Predictive Value will be evaluated in relation to: a) limit of detection of the used assay b) 99th percentile of the reference healthy population Evaluation of 30-day prognosis Evaluation of costs of any further examinations after the first
Safety evaluation	N.A. (already provided in the Hospital)
Expected number of patients	500 patients for each Centre
Type of patients	Patients with suspected acute myocardial infarction and non-ST-elevation ECG (NSTEMI) at admission at the Emergency Department
Type and number of centres	12 Emergency Departments
Enrollment	Consecutive
Number of examinations	Patients will be examined at enrollment in the Emergency Departments, and after 30-days
Inclusion and exclusion criteria	**Inclusion criteria** • both sexes • ≥18 years old • Patients with chest pain • At least one high-sensitivity cardiac troponin test performed • Written informed consent

	Exclusion criteria • Refusal to provide informed consent • Elevation of ST segment in the ECG • Pregnancy or breastfeeding • Any other clinical conditions not compatible with participation at the study
Used in-vitro medical device	Different quantitative assays of high-sensitivity cardiac troponin currently available and used in the Emergency Department
Length of study	January 2018 - July 2018

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