Troponine-At-Bedside study

Submission date	Recruitment status No longer recruiting	Prospectively registered		
04/08/2007		☐ Protocol		
Registration date 09/08/2007	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
29/10/2021	Circulatory System			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number 00-035

Study information

Scientific Title

Troponine-At-Bedside study

Acronym

TAB

Study objectives

We hypothesized that Point of Care Testing in the emergency department for troponin I measurement would be associated with a faster process of care, including for patients presenting with non specific symptoms.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Institutional Review Board for the Protection of Human Subjects of Henri Mondor Hospital approved the study protocol and patient informed consent procedures in June 2002.

Study design

Randomized controlled trial.

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Acute coronary syndrome

Interventions

Point-Of-Care testing in the emergency department vs central hospital laboratory testing for troponin I measurement.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Time to anti-ischemic therapy.

Key secondary outcome(s))

- 1. Time to physician notification of troponin I level
- 2. Length of stay within the emergency department defined by the time to bed assignment
- 3. Mortality at 30 and 90 days after presentation
- 4. Level of emergency department staff reliability on Point-Of-Care testing versus central hospital laboratory testing as assessed by the proportion of second troponin I tests ordered after the Point-Of-Care testing

Completion date

31/07/2004

Eligibility

Key inclusion criteria

- 1. Age 18 years or older
- 2. Suspicion of acute coronary syndrom
- 3. Required to measure troponin I (Ti)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

833

Key exclusion criteria

1. Patients presenting with ST-elevation Acute Coronary Syndrome (ACS) (typical chest pain and persistent [>20 min] ST-segment elevation [>0.1 mV in limb leads or 0.2 mV in precordial leads]) did not represent such a diagnostic challenge compared to NSTE-ACS and were candidate for urgent reperfusion procedure, and therefore were excluded from the current analysis.

Other exclusion criteria:

- 2. Refusal or inability to provide informed consent
- 3. Previous enrolment in the study

Additionally, aiming to select patients with high risk ACS, the patients who had 1-2 Ti levels consistently <0.10 μ g/L within eight hours of the onset of ACS symptoms were excluded from the study post-hoc.

Date of first enrolment

01/11/2002

Date of final enrolment

31/07/2004

Locations

Countries of recruitment

France

Study participating centre

GHU Henri Mondor-Albert Chenevier

Créteil France 94010 Cedex

Sponsor information

Organisation

Dade Behring (France)

ROR

https://ror.org/04q9w3z30

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

The Henri Mondor Hospital (France)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/02/2008	29/10/2021	Yes	No