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Troponine-At-Bedside study

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

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 measure
Time to anti-ischemic therapy.

Secondary outcome measures

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

Overall study start date
01/11/2002

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
800

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 µg/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)

Sponsor details
Immeuble Le Berkeley
19-29 rue du Capitaine Guynemer
Paris La Défense
France
92903 Cedex

Sponsor type
Industry

ROR
https://ror.org/04q9w3z30

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
The Henri Mondor Hospital (France)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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