

Troponine-At-Bedside study

Submission date 04/08/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/08/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/10/2021	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Bertrand Renaud

Contact details

GHU Henri Mondor-Albert Chenevier
51, avenue du Maréchal Delattre de Tassigny
Créteil
France
94010 Cedex

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 NSTEMI-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