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Pre-hospital identification of prognostic biomarkers in time-dependent diseases

Submission date	**Recruitment status**	[X] Prospectively registered
31/10/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/11/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/04/2025	Other	

Plain English summary of protocol

Background and study aims
Time-dependent diseases represent one of the most frequent causes of care by the Emergency Medical Services (EMS), one of the most frequent reasons for hospitalization and one of the main potential causes of early mortality. Health systems are making efforts to implement protocols for the management of this specific type of pathologies (infarction code, ICTUS, sepsis, etc). Being aware of the pathophysiological situation of the patient is essential to manage the situation, where early diagnosis is essential. The EMS perform standard advanced life support manoeuvres, with a wide technical capacity, but with very limited diagnostic means. For this reason, the general objective is to evaluate the prognostic capacity of the National Early Warning Score 2 scale, of prehospital analysis and of the joint level capnometry data (HITS score), to predict early mortality (before 48 hours) from the index event.

Who can participate?
Patients attended by Advanced Life Support (ALS) in the province of Valladolid

What does the study involve?
Patients undergo a structured and objective evaluation according to protocol and proceed to its stabilization. Respiratory rate, saturation, heart rate, blood pressure, temperate, coma scale score, and blood levels of lactic acid and glycemia values are measured. Once the patient is left in the Emergency Department they follow the normal course of treatment. 30 days after the index event (ALSU's attention at the scene) an analysis of the electronic clinical history of the participant is made to collect data on their hospital care and mortality data. At this moment, the observation will end. No interventions are performed on patients depending on the HITScore scale, but if the analytical or physiological data indicate urgent pathology, it will be acted on according to the EMS operating procedures. All participants receive the most appropriate treatment for their situation, regardless of the results of the study.

What are the possible benefits and risks of participating?
Through the use of this early warning scale, the clinical safety of patients is increased since the health system can perform a comprehensive follow-up of their situation. The scale also uses language easily understood by patients and professionals, which helps to facilitate the transmission of information. A delay in the timely identification of the critical pathology of the

patient has a direct impact on the health system, with an increase in diagnostic procedures and surgical techniques, hospitalizations, stays in intensive care units or unexpected deaths. With the early identification of patients at high risk, it is intended to reduce morbidity and mortality. There are no known risks to participants taking part in this study.

Where is the study run from?
Health Emergency Management of Castilla y León (Spain), University Clinical Hospital of Valladolid (Spain), Rio Hortega University Hospital (Spain).

When is the study starting and how long is it expected to run for?
November 2019 to December 2023

Who is funding the study?
Regional Health Management of Castilla y León (SACYL) (Spain)

Who is the main contact?
Francisco Martín-Rodríguez
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
GRS/1903/A/19

Study information

Scientific Title
Predictive value of biological, physiological and analytical biomarkers in the prehospital scope: observational, prospective, analytical, non-intervention and multicenter study

Acronym
HITScore

Study objectives
Evaluate the prognostic capacity of different early warning scales (EWS, NEWS2, qSOFA, etc.), analytical biomarkers, and ETCO2 data, separately and at the joint level (HITS score) obtained at the prehospital level, to predict early mortality (before 48 hours) from the index event.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 07/10/2019, Comité de Ética de la Investigación con Medicamentos Área de Salud Valladolid Este (Hospital Clínico Valladolid, Facultad de Medicina, Farmacología, C/ Ramón y Cajal, 7 47005 Valladolid, España; Tel: 983 42 30 77; Email: alvarez@med.uva.es, jalvarezgo@saludcastillayleon.es), ref: PI-GR-19-1258
2. Approved 05/03/2019, CEIC Área de Salud de Valladolid Oeste (Hospital Universitario Río Hortega, 47012 Valladolid (Valladolid); Tel: 983 420 400; Email: rconvi@saludcastillayleon.es), ref: PI041-19

Study design
Observational prospective cross-sectional cohort analytical non-intervention and multicenter study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Early mortality in all types of patients without evident signs of severity

Interventions
Patients and/or participants undergo a structured and objective evaluation according to protocol and proceed to its stabilization. The physiological variables are collected (respiratory rate, saturation, heart rate, blood pressure, temperate, coma scale score), and blood determination (capillary or venous if it is channeled via venous) of lactic acid and glycemia values is completed.

Once the patient is left in the Emergency Department they will follow the normal course of treatment. 30 days after the index event (ALSU's attention at the scene) an analysis of the electronic clinical history of the participant is made to collect the data of their hospital care and mortality data. At this moment, the observation will end.

Intervention Type
Mixed

Primary outcome measure
The following are evaluated at first attention at the scene of the incident:
1. Respiratory frequency, assessed using clinical observation at baseline
2. Oxygen saturation, assessed using a Physio LifePAK® 15 monitor at baseline
3. Non invasive ETCO2, assessed using a Physio LifePAK® 15 monitor at baseline
4. Heart rate, assessed using a Physio LifePAK® 15 monitor at baseline
5. Blood pressure, assessed using a Physio LifePAK® 15 monitor at baseline
6. Tympanic temperature assessed using a Braun model ThermoScan® PRO 6000 at baseline
7. Patient consciousness, assessed using the Glasgow Coma Scale at baseline
8. Use of oxygen (or not), evaluated using clinical observation at baseline
9. Analytical biomarkers: pH, pCO2, pO2, cHCO3-, BE (ecf), cSO2, Na +, K +, Ca ++, Cl-, TCO2, Agap, AGapK, Hct, Hb, BE (b), Glu, Lac, BUN, Urea and Crea, assessed using EPOC Siemens Healthcare at baseline
10. Electrocardiogram assessed using a Physio LifePAK® 15 monitor at baseline
11. Initial and route FiO2 assessed using a Physio LifePAK® 15 monitor at baseline
12. Prehospital diagnosis according to the Medical Priority Dispatch System incident code at baseline

Secondary outcome measures
1. Early mortality at 48 hours
2. Presence of serious adverse events in prehospital scope at baseline
3. Presence of serious adverse events in hospital at 48 hours
4. Need for Intensive Care Unit at 30 days
5. Mortality from any cause at 30 days

Overall study start date
15/11/2019

Completion date
31/12/2023

Eligibility

Key inclusion criteria

1. Treated by an ALSU
2. Aged over 18 years
3. Provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
900

Total final enrolment
1114

Key exclusion criteria
1. Aged under 18 years
2. Cardiorespiratory arrest or exitus prior to arrival at the hospital
3. Pregnant
4. Psychiatric pathology
5. Diagnosis of end-stage disease (in treatment at a palliative care unit)
6. ALSU takes longer than 45 minutes to arrive
7. Evacuated by transport other than ambulance
8. Do not require transfer to the hospital

Date of first enrolment
01/12/2019

Date of final enrolment
30/10/2021

Locations

Countries of recruitment
Spain

Study participating centre
Gerencia de Emergencias Sanitarias de Castilla y León
C/ Antiguo Hospital Militar, s/n
Valladolid
Spain
47006

Sponsor information

Organisation
Gerencia de Emergencias Sanitarias de Castilla y León

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Sponsor type
Government

Website
https://www.saludcastillayleon.es/ciudadanos/es/urgencias-emergencias/emergencias-sanitarias-castilla-leon

ROR
https://ror.org/02s8dab97

Funder(s)

Funder type
Government

Funder Name
Gerencia Regional de Salud de Castilla y León

Funder Name
Universidad de Valladolid

Alternative Name(s)
University of Valladolid, UVA

Funding Body Type
Government organisation

Funding Body Subtype

Local government

Location
Spain

Results and Publications

Publication and dissemination plan
There is a study protocol and analysis plan that can be sent upon reasonable request.

The research team will promote the dissemination of the results obtained in various scientific publications:
1. American Journal of Medicine
2. Critical Care Medicine
3. Emergencies
4. Intensive Care Medicine
5. Prehospital & Emergency Care
6. Resuscitation
If external funding is obtained, communications could be sent to the main international emergency and emergencies forums

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from (F. Martín-Rodríguez, fmartin@saludcastillayleon.es). Statistical data will be available from the end of the data collection phase for 4 years. The data may be shared with researchers carrying out similar studies, provided that the exchange of information is mutual, by sending the anonymized data of patients. Patients will have signed informed consent for data sharing.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/06/2021	06/07/2021	Yes	No
Results article	Prehospital point-of-care medication burden	02/08/2024	23/04/2025	Yes	No