

# Identification of biomarkers of clinical-risk deterioration in prehospital care

<b>Submission date</b> 20/02/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/02/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/04/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Time-dependent diseases (cardiac arrest, stroke, heart attack, sepsis and trauma) are one of the most frequent causes of medical consultation, activation of the emergency medical services (EMS), and consequently referral to the emergency department (ED).

The main objective of this study is to develop a specific score to be used in prehospital care with the ability to discriminate the risk of clinical deterioration from the initial moments of prehospital care.

### Who can participate?

Patients attended by Advanced Life Support (ALS) in the community of Castilla y León.

### 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, temperature, coma scale score, and a complete analysis is carried out (ions, blood gas, cardiac enzymes, coagulation and basic biochemistry). 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. After one year of follow-up, a new data collection is carried out, in order to observe mortality from any cause, both in-hospital and out-hospital. At this moment, the observation will end. No interventions are performed on patients depending on the outcomes, 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 early warning scale and biomarkers, 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), including 23 ALSU, and 14 hospitals, all belonging to the Public Health System of Castilla y León (Spain).

When is the study starting and how long is it expected to run for?

November 2020 to December 2024

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)**

Scientific

**Contact name**

Prof Francisco Martín-Rodríguez

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**Contact details**

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

A.200/a1

## Study information

## Scientific Title

Novel prehospital scores and outcomes based on biomarkers bedside: prospective, multicentric, ambulance-based, EMS-delivery, observational study

## Acronym

preBIOs

## Study objectives

Analyze all available biomarkers bedside or en route in order to develop an early warning score adapted to prehospital care, with the capacity to detect the risk of short-term deterioration in frail patients or the risk of early mortality from the index event.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. Approved 05/11/2020, 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; +34 983 42 30 77; alvarezgo@saludcastillayleon.es), ref: PI-GR-20-1970.
2. Approved 24/11/2020, CEIC Área de Salud de Valladolid Oeste (Hospital Universitario Río Hortega, 47012 Valladolid (Valladolid); +34 983 420 400; rconvi@saludcastillayleon.es), ref: PI217-20.
3. Approved 05/11/2020, CEIC Área de Salud de Salamanca (Complejo Asistencial Universitario de Salamanca, 37007 Salamanca (Salamanca); +34 923 29 11 00; comite.etico.husa@saludcastillayleon.es), ref: PI 2020 10 573

## Study design

Prospective multicentric ambulance-based EMS-delivery observational study

## Primary study design

Observational

## Study type(s)

Diagnostic

## Health condition(s) or problem(s) studied

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

## Interventions

Once the patient (or legal guardian) signs the informed consent form, he/she becomes part of the study. Vital signs are taken and a blood sample is taken from the venous line, which is inserted due to the need of their own pathology, not for participating in the study. The prehospital analysis is then performed with this venous sample.

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, temperature, coma scale score) and blood determination.

## Intervention Type

Mixed

## **Primary outcome(s)**

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. Heart rate, assessed using a Physio LifePAK® 15 monitor at baseline
4. Blood pressure, assessed using a Physio LifePAK® 15 monitor at baseline
5. Tympanic temperature assessed using a Braun model ThermoScan® PRO 6000 at baseline
6. Patient consciousness, assessed using the Glasgow Coma Scale at baseline
7. Use of oxygen (or not), evaluated using clinical observation at baseline
8. Analytical biomarkers: pH, pCO<sub>2</sub>, pO<sub>2</sub>, cHCO<sub>3</sub><sup>-</sup>, BE (ecf), cSO<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, Cl<sup>-</sup>, TCO<sub>2</sub>, Agap, AGapK, Hct, Hb, BE (b), Glu, Lac, BUN, Urea and Crea, assessed using EPOC Siemens Healthcare at baseline, cardiac enzymes (proBNP, myoglobin, CK, D dimer and troponin) with Roche Cobas 232 and INR with Roche coagucheck
9. Electrocardiogram assessed using a Physio LifePAK® 15 monitor at baseline
10. Initial and route FiO<sub>2</sub> assessed using a Physio LifePAK® 15 monitor at baseline

The following are evaluated before arrival at the hospital:

1. Respiratory frequency, assessed using clinical observation at baseline
2. Oxygen saturation, assessed using a Physio LifePAK® 15 monitor at baseline
3. Heart rate, assessed using a Physio LifePAK® 15 monitor at baseline
4. Blood pressure, assessed using a Physio LifePAK® 15 monitor at baseline
5. Tympanic temperature assessed using a Braun model ThermoScan® PRO 6000 at baseline
6. Patient consciousness, assessed using the Glasgow Coma Scale at baseline
7. Use of oxygen (or not), evaluated using clinical observation at baseline
8. Prehospital diagnosis according to the Medical Priority Dispatch System incident code at baseline

## **Key secondary outcome(s)**

1. Mortality at 1, 2, 7, 14 and 28 days
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. Out-of-hospital mortality during a follow-up period of up to 1 year
6. Analytical data from the first blood draw at the hospital: leukocytes, hemoglobin, hematocrit, platelets, sodium, potassium, calcium, chloride, glucose, creatinine, bilirubin, CRP, PCT, troponin, D-dimer, proBNP and CK
7. Comorbidities
8. Triage level in the first contact in the emergency department

## **Completion date**

31/12/2024

## **Eligibility**

### **Key inclusion criteria**

1. Evaluated by an EMS
2. Transfer to hospital in advanced or basic life support.
3. Aged over 18 years
4. Provide informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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. Do not require transfer to the hospital

**Date of first enrolment**

01/04/2021

**Date of final enrolment**

31/10/2024

**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

**Study participating centre**

Facultad de Medicina. Universidad de Valladolid

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Valladolid  
Spain  
47005

## Sponsor information

### Organisation

Junta de Castilla y León

### ROR

<https://ror.org/02s8dab97>

## Funder(s)

### Funder type

Government

### Funder Name

Junta de Castilla y León

### Alternative Name(s)

Junta of Castile and León, Regional Government of Castilla y León, JCYL

### Funding Body Type

Government organisation

### Funding Body Subtype

Local government

### Location

Spain

## Results and Publications

### 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](mailto: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?
<a href="#">Results article</a>		02/08/2024	23/04/2025	Yes	No