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Use of early warning scales in the prehospital scope as a diagnostic and prognostic tool

Submission date
21/10/2018

Recruitment status
No longer recruiting

Registration date
26/10/2018

Overall study status
Completed

Last Edited
24/09/2021

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The early detection of time-dependent diseases is a priority of health systems. The National Early Warning Score 2 (NEWS2) is a tool capable of identifying subtle signs of deterioration, hours before a serious adverse event. By using this scale, it is possible to detect sensitive patients at high risk.
Another tool that can help reduce diagnostic uncertainty are portable analytical devices, which reduce the time window from the beginning of the symptoms to a diagnosis. One such tool measures lactic acid levels.
Scales and tools cannot substitute a correct objective and structured clinical evaluation, but we believe that the proposed new scale, called prehospital NEWS2-Lactate (preNEWS2-L), composed of the NEWS2 scale and lactic acid levels, which can help to guide professionals in their practice.

Who can participate?
Patients who are assisted by ALSU in the different cities involved in the study and transferred to the Emergency Department of their referral hospital.

What does the study involve?
Once assistance is complete, a researcher in each ALSU is in charge of collecting from the emergency medical record demographic variables (sex and age), reason for calling (medical pathology, traffic accident, labor or casual, social demand or other), times of arrival, assistance and transfer, and clinical variables necessary to be able to carry out the NEWS2. Aanalytical variables were also collected, including the level of blood glucose and lactic acid in venous blood. Subsequently, a researcher in each hospital monitored the electronic history of the patient 30 days after emergency care to collect their final diagnosis, complementary tests (ultrasound, endoscopy and/or scan), surgical interventions, destination in the hospital (discharge or admission), need for Intensive Care Unit (ICU) and days of admission.

What are the possible benefits and risks of participating?
Through the implementation of this application 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?
1. Gerencia de Emergencias Sanitarias de Castilla y León (Spain)
2. Hospital Clínico Universitario de Valladolid (Spain)
3. Hospital Universitario Rio Hortega (Spain)

When is the study starting and how long is it expected to run for?
January 2018 to May 2020

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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GRS-1678/A/18

Study information

Scientific Title
Longitudinal observational study to evaluate the use of the prehospital scale National Early Warning Score Lactate (preNEWS-L)

Acronym
preNEWS-L

Study objectives
The working hypothesis consists of evaluating the use of the pre-NEWS-L scale as a diagnostic tool in the prehospital setting. We want to verify if this scale is able to predict with a high degree of efficiency the early mortality at 2 and 7 days

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved on 9 March 2018,
Clinical Research Ethics Committee at the Río Hortega University Hospital and the University Clinic Valladolid (Spain), 09/03/2018, registration codes #PI 18-010 & #PI 18-895 (respectively)

Study design
Observational prospective longitudinal study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Other

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 assessed at first attention at the scene of the incident:
1. Respiratory frequency, assessed using clinical observation
2. Oxygen saturation, assessed using a Physio LifePAK® 15 monitor
3. Heart rate, assessed using a Physio LifePAK® 15 monitor
4. Blood pressure, assessed using a Physio LifePAK® 15 monitor
5. Tympanic temperature assessed using a Braun model ThermoScan® PRO 6000
6. Patient consciousness, assessed using the Glasgow Coma Scale
7. Use of oxygen (or not), assessed using clinical observation
8. Lactic acid levels, assessed using an Accutrend® Plus meter
9. Blood glucose, assessed using an Accu-Chek® Aviva

Secondary outcome measures
The following are assessed using a review of electronic medical records within 30 days of the index event:
1. Main diagnosis
2. Mortality
3. Days of admission
4. Need for ICU
5. Complementary tests requested

Overall study start date
30/10/2019

Completion date
02/05/2020

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
937

Total final enrolment
3081

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
01/04/2018

Date of final enrolment
30/10/2019

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
Hospital Clínico Universitario de Valladolid
Avda. Ramón y Cajal nº3
Valladolid
Spain
47003

Study participating centre

Hospital Universitario Rio Hortega
Calle Dulzaina, 2
Valladolid
Spain
47012

Sponsor information

Organisation
Gerencia de Emergencias Sanitarias de Castilla y León

Sponsor details
Calle Antiguo Hospital Militar 2ª planta
Valladolid
Spain
47006

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/02s8dab97

Funder(s)

Funder type
Not defined

Funder Name
Gerencia Regional de Salud

Results and Publications

Publication and dissemination plan
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
01/06/2019

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	results	01/12/2019	09/12/2019	Yes	No
Results article	results	01/02/2020	09/12/2019	Yes	No
Results article	results	01/06/2019	09/12/2019	Yes	No
Results article	results	01/09/2019	09/12/2019	Yes	No
Results article		01/06/2020	24/09/2021	Yes	No