

Survival of patients suffering an out-of-hospital cardiac arrest treated by emergency services in Spain during the COVID-19 pandemic and 1 year later

Submission date 11/05/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/05/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/01/2024	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Out-of-hospital cardiac arrest (OHCA) (heart attack) is a major public health problem. Patient survival depends on a series of precise and coordinated actions that must be established from the moment of patient collapse. Society, the citizens themselves, are a fundamental part of the chain of survival.

The current COVID-19 pandemic has caused a series of changes in patient care that have a very important influence in the case of OHCA. The possibility of contagion has forced two major changes: emergency teams must take precautions and there are more restrictions for recommending an initial citizen intervention. Delays and reduced witnessed resuscitation may affect survival after OHCA. Researchers do not know their real influence, whether they will be maintained even when the pandemic ends, or if they will affect future CPR recommendations.

Who can participate?

OHCA patients treated with resuscitation by the emergency services or who received post-resuscitation care after cardiopulmonary resuscitation (CPR) attempts by a first responder

What does the study involve?

The incidence of resuscitation attempts, general characteristics, and survival at discharge of patients are all measured from medical records during the COVID-19 pandemic and the same 3 months 2 years later, in 2022.

What are the possible benefits and risks of participating?

The study will show the impact of the pandemic on the different links of the chain of survival and if these changes keep over time.

Where is the study run from?

Emergency services in 15 Spanish regions

When is the study starting and how long is it expected to run for?
January 2020 to July 2023

Who is funding the study?
Spanish Resuscitation Council

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
OHSCAR 3

Study information

Scientific Title
Survival of patients suffering an out-of-hospital cardiac arrest treated by emergency services in Spain

Acronym

OHSCAR

Study objectives

A pandemic situation changes the real practice for out-of-hospital cardiac arrest management.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 03/07/2020, Research Ethics Committee, Department of Health of the Government of Navarra (Pabellón de Docencia (Teaching Pavilion). Irunlarrea 3, Pamplona 31 008, Spain; +34 (0) 848822495; no email address provided), ref: PI_2020/60

Approved 29/07/2020, Drug Research Ethics Committee of La Rioja (Edificio CIBIR. Piqueras 98, 3ª planta. 26006 Logroño. La Rioja, Spain; +34 (0)941 278855; secretaria.ceic@riojasalud.es), ref: CEImLAR P.I. 427

Study design

Observational retrospective multicentre study

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Other

Study type(s)

Treatment

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

Out-of-hospital cardiac arrest (OHCA)

Interventions

Continuous registry of OHCA patients according to Utstein style guidelines to determine the incidence, general characteristics, and survival at discharge of patients attended by Spanish emergency services. The researchers use pre-hospital medical records provided by emergency services and in-hospital medical records, only in cases with successful resuscitation, to assess in-hospital evolution and status at discharge.

First phase: 01/02/2020 to 31/03/2020. Three months during the rise, stabilisation and decline of the COVID-19 pandemic in Spain.

Second phase: 01/02/2021 to 31/03/2021. The same 3 months 1 year later.

Updated 30/12/2021:

Second phase: Inclusion period, 1 year from 01/01/2022 to 31/12/2022.

Intervention Type

Other

Primary outcome measure

Survival at hospital discharge with good neurological status, expressed as percentage of patients with Cerebral Performance Category scale ≤ 2 , during the COVID-19 pandemic and 1 year later

Secondary outcome measures

Measured using medical records during the COVID-19 pandemic and 1 year later:

1. Incidence of resuscitation attempts expressed as the number of resuscitations attempts per 105 inhabitants
2. Bystander reanimation expressed as percentage of cases with bystander reanimation excluding those cases witnessed by emergency teams
3. Airway management expressed as percentage of cases with airway isolation

Overall study start date

23/01/2020

Completion date

31/07/2023

Eligibility

Key inclusion criteria

Cases of OHCA in which an EMS performed resuscitation or post-resuscitation care after cardiopulmonary resuscitation (CPR) attempts by a first responder

Participant type(s)

Patient

Age group

Mixed

Sex

Both

Target number of participants

In Spain there are 17 emergency public services (17 regions). At the moment there 13 of them are involved (more than 80% of Spanish total population). Based on previous data, the researchers estimate about 2000 – 2500 cases per three months period.

Total final enrolment

8629

Key exclusion criteria

Cases in which the EMS suspended resuscitation on the grounds that it was not indicated due to futility criteria confirmed during resuscitation. An attempt at CPR was considered futile when new data during resuscitation showed that it was not indicated (terminal disease, prolonged arrest time prior to EMS arrival, "Do not resuscitate" orders)

Date of first enrolment

01/02/2020

Date of final enrolment

31/12/2022

Locations

Countries of recruitment

Spain

Study participating centre

Servicio de Urgencias y emergencias Médicas 061 de La Rioja

Hospital San Pedro

C/ Piqueras 92

Logroño

Spain

26006

Study participating centre

Servicio de Urgencia Médica de la Comunidad de Madrid, SUMMA 112

Antracita 2, bis

Madrid

Spain

28045

Study participating centre

Subdirección de urgencias y atención a la urgencia vital de Navarra

Plaza de la Paz s/n

Pamplona

Spain

31002

Study participating centre

Emergentziak Osakidetza

María Díaz de Haro 53

Bilbao
Spain
48010

Study participating centre

061 Aragón

Avenida Navarra 78, 2ª planta
Zaragoza
Spain
50011

Study participating centre

Gerencia de Emergencias Sanitarias de Castilla y León

Paseo Hospital Militar 24-2
Valladolid
Spain
47007

Study participating centre

Emergencies Mediques. Departament de Salut.

Pablo Iglesias, 101-115
L'Hospitalet de Llobregat
Spain
08908

Study participating centre

SAMUR - Protección Civil

Ronda de las Provincias, 7
Madrid
Spain
28011

Study participating centre

Urxencias sanitarias 061

Rúa da Cultura, s / n
A Estrada (Pontevedra)
Spain
36680

Study participating centre**Gerencia de urgencias y emergencias 061 del Servicio Murciano de Salud**

Calle escultor José Sánchez Lozano 7 segunda planta

Murcia

Spain

30005

Study participating centre**Servicio de Emergencias 061 Cantabria**

Rosalía de Castro s/n

Santander

Spain

39011

Study participating centre**Servicio de Atención Médica Urgent 061 de las Islas Baleares**

Carrer Illes Balears, 1B

Palma de Mallorca

Spain

07014

Study participating centre**Emergencias Sanitarias de Extremadura 112**

Subdirección de Atención Primaria.

AVD de la Américas nº 2.

Mérida

Badajoz

Spain

06800

Study participating centre**Servicio de Emergencias Sanitarias, Comunidad Valenciana**

Avenida Campanar

21 - 5 A Planta Escola Enf la Fe

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Valencia

Spain

46009

Sponsor information

Organisation

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061@sergas.es

Sponsor type

Other

Website

<https://061.sergas.gal/Paxinas/web.aspx>

Organisation

SEM - Sistema d'Emergències Mèdiques

Sponsor details

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Hospitalet de Llobregat
Spain
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+34 (0)9326444 00
sem@gencat.cat

Sponsor type

Other

Website

<http://sem.gencat.cat/ca/contacte/>

Organisation

Andalusian School of Public Health

Sponsor details

Cuesta del Observatorio 4
Campus Universitario de Cartuja
Granada
Spain
18080
+34 (0)958027400
comunicacion.easp@juntadeandalucia.es

Sponsor type

University/education

Website

<https://www.easp.es/>

ROR

<https://ror.org/05wrpbp17>

Funder(s)

Funder type

Other

Funder Name

Spanish Resuscitation Council

Results and Publications

Publication and dissemination plan

The first publication: Incidence, characteristics and survival of OHCA during a pandemic in Spain: summer 2020 (results of three months of 2020).

Two later publications at the end of 2021:

1. Incidence, characteristics, and survival of OHCA 1 year after the COVID-19 pandemic in Spain
2. Changes in first links of the chain of survival due to a COVID-19 pandemic. Results of the Spanish registry of OHCA

Intention to publish date

31/12/2023

Individual participant data (IPD) sharing plan

The data provided by the participating emergency services are anonymous. In Spain, every health service has the duty to safeguard its medical records, as well as to control their quality. The variables of each case are transcribed into a standardized database, homogeneous for the study, and which follows the definitions of the Utstein 2014 style.

The project uses exclusively coded tables, exported by the EMS involved in Excel or SPSS for subsequent statistical analysis. It is not possible to identify and correlate the data in the database with specific patients. Each service requests the appropriate consents from the reference ethics committees. In general, Spanish legislation allows the use of anonymized data from patients' medical records to evaluate health outcomes.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2020	16/10/2020	Yes	No
Results article		02/01/2024	29/01/2024	Yes	No