

Prehospital recognition and antibiotics for 999 patients with severe sepsis

Submission date 16/05/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 24/05/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/09/2021	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Sepsis is a rare but serious complication of an infection. It kills between 36,000 and 64,000 people every year in the UK. Early diagnosis and treatment of sepsis has been shown to reduce the risk of death and improve health and well-being. Paramedics frequently come into contact with patients with sepsis, and are well placed to provide early diagnosis and treatment. This small study aims to find out whether paramedics can collect blood samples and give antibiotics to patients with severe sepsis. The aim is to find out whether it is feasible, safe and acceptable, so that a decision can be made about whether to proceed to a full study, which can confirm whether it is effective for patients and worthwhile for the NHS.

Who can participate?

Patients aged 18 and over, treated by participating paramedics and suspected of having severe 'Red Flag' sepsis

What does the study involve?

Participating paramedics receive training to assist them to recognise severe sepsis. If severe 'Red Flag' sepsis is suspected, paramedics randomly select a scratchcard, which informs them whether to provide enhanced care or usual care to the patient. All patients treated by the participating paramedics benefit from an enhanced level of assessment because of the additional training the paramedics receive. In addition to usual care, paramedics treating patients with enhanced care collect blood samples and give a first dose of intravenous antibiotics (into a vein) before the patient arrives at the hospital. Some of the patients are interviewed later and a focus group is held with paramedics to find out what they think about the intervention.

What are the possible benefits and risks of participating?

Participants may benefit from early antibiotic treatment. The antibiotic cefotaxime has already been confirmed to be safe and effective for the treatment of severe sepsis and is not under scrutiny in this study. Cefotaxime is widely used, generally well tolerated, and is the locally approved broad-spectrum antibiotic for the treatment of sepsis in Cardiff and Vale University Health Board. It is given to patients on admission to hospital as part of standard care. The more common side effects include diarrhoea, nausea, or abdominal discomfort, and are usually mild

and temporary. Rarely observed side effects include allergic reactions, with the potential for anaphylaxis (a severe allergic reaction). Treatment of anaphylactic reactions is routine for paramedics, who have access to adrenaline and salbutamol for treating symptoms. Therefore the potential benefits of early use of cefotaxime by paramedics far outweigh the risks of an anaphylactic reaction. Participants who agree to follow up at 90 days may feel inconvenienced or experience a sense of intrusion when contacted. Before beginning the questionnaire process, participants are asked whether it is a convenient time for them and if not, an alternative time and date is arranged. Follow-up contact in the form of face-to-face meetings, postal correspondence and telephone calls is conducted in a friendly, courteous and timely manner.

Where is the study run from?
University Hospital Wales (UK)

When is the study starting and how long is it expected to run for?
March 2017 to February 2019

Who is funding the study?
Health and Care Research Wales (UK)

Who is the main contact?
Dr Jenna Bulger
j.k.bulger@swansea.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Jenna Bulger

ORCID ID
<http://orcid.org/0000-0002-1280-4941>

Contact details
ILS2, Singleton Park
Swansea
United Kingdom
SA2 8PP
+44 (0)179 251 3424
j.k.bulger@swansea.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1

Study information

Scientific Title

Prehospital Recognition and Antibiotics for 999 patients with Severe sepsis (PHRASE): a feasibility study

Acronym

PHRASE

Study objectives

That paramedics are able take blood cultures from and provide intravenous antibiotics to patients with severe sepsis in the prehospital environment before the patients arrives at the emergency department.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Wales Research Ethics Committee 4, ref: 17-WA-0186

Study design

Individually randomised feasibility study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Sepsis

Interventions

Sixty paramedics will be recruited to the study and will receive an enhanced level of training to assist them to recognise severe sepsis. If severe 'Red Flag' sepsis is suspected, paramedics will select a scratchcard, which will inform them whether to provide enhanced care (intervention), or usual care (control). All patients managed by study paramedics will benefit from an enhanced level of assessment, because of the additional training the paramedics are provided in

recognition of sepsis. In addition to usual care, paramedics treating patients in the intervention arm will collect prehospital blood cultures and give a first dose of intravenous antibiotics. 10 patients will be interviewed and a focus group will be held with paramedics to find out what they think about the intervention. Both groups will have follow up at 90 days, where they are sent a self reported quality of life questionnaire or it is recorded that the patient has died.

Intervention Type

Other

Primary outcome measure

The feasibility of undertaking a randomised controlled trial (RCT) to test the clinical and cost-effectiveness of paramedics providing IV antibiotics as early treatment for patients with severe sepsis. The trialists will assess whether or not to proceed to a full multi-site RCT based on the following progression criteria:

1. 60% of the 100 eligible paramedics agree to take part in the study
2. 70% of eligible patients consent to take part in the study
3. Follow-up data for potential primary outcomes can be collected for 70% or more of patients at 90 days
4. Mean patient satisfaction in intervention group is not less than 80% of patient satisfaction in the control group
5. Feasibility trial findings indicate that they remain in equipoise about the effectiveness of paramedic collection of blood cultures and antibiotic administration (i.e. that delivery of the intervention does not exceed a greater than 20-minute difference in on-scene times for patients compared to those in the control group)
6. Adverse event rate (e.g. allergic (anaphylactic) reactions to antibiotics) of less than 5%

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/03/2017

Completion date

28/02/2019

Eligibility

Key inclusion criteria

1. Adult patients 18 years of age and above
2. Attended by study paramedics
3. Identified as 'Red Flag' sepsis
4. Admitted to participating hospital

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Total final enrolment

118

Key exclusion criteria

1. Pregnancy (known or suspected)
2. Known history of allergy to antibiotics

Date of first enrolment

01/11/2017

Date of final enrolment

31/05/2018

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

University Hospital Wales

Heath Park

Cardiff

United Kingdom

CF14 4XN

Sponsor information

Organisation

Wales Ambulance Services NHS Trust

Sponsor details

Prehospital Emergency Research Unit

Lansdowne Hospital

Sanatorium Road

Cardiff

United Kingdom
CF11 8PL

Sponsor type

Research organisation

ROR

<https://ror.org/017qpw206>

Funder(s)

Funder type

Government

Funder Name

Health and Care Research Wales

Results and Publications

Publication and dissemination plan

The trialists plan to submit the protocol for publication to an appropriate journal after it has received ethics approval. Results of this feasibility trial will be available for publication in a peer-reviewed journal in approximately Spring 2019.

Intention to publish date

01/03/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Swansea Trials Unit, ILS2, Singleton Campus, SA2 8PP.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2.1	07/08/2017	30/08/2017	No	Yes
Protocol article	protocol	12/03/2018		Yes	No
Results article	Results	20/09/2021	22/09/2021	Yes	No