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Prehospital recognition and antibiotics for 999 patients with severe sepsis

Submission date
16/05/2017

Recruitment status
No longer recruiting

Registration date
24/05/2017

Overall study status
Completed

Last Edited
22/09/2021

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Individually randomised feasibility study

Study type(s)
Treatment

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(s)
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%

Key secondary outcome(s)
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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

ROR
https://ror.org/017qpw206

Funder(s)

Funder type
Government

Funder Name
Health and Care Research Wales

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 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?
Results article	Results	20/09/2021	22/09/2021	Yes	No
Protocol article	protocol	12/03/2018		Yes	No
Participant information sheet	version V2.1	07/08/2017	30/08/2017	No	Yes