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Defining sepsis on the wards

Submission date
09/05/2016

Recruitment status
No longer recruiting

Registration date
17/06/2016

Overall study status
Completed

Last Edited
10/07/2023

Condition category
Infections and Infestations

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sepsis is a potentially life-threatening condition, in which the body's immune system goes into overdrive in response to an infection, causing widespread inflammation (swelling). Severe sepsis is the name used when the sepsis causes one or more of the body's systems, such as the heart, liver or kidneys, to stop working properly (organ failure).In order to prevent this, it is vital that sepsis is recognised and treated quickly, with appropriate escalation to critical care (emergency care) if required. It has also been found that a patient with sepsis is five times more likely to die than a patient who has suffered a heart attack or stroke. In the UK, sepsis is estimated to be responsible for about 37,000 deaths every year at a cost of £2.5 billion, which in Wales this could equate to a figure of 1,800 deaths and a cost of £125 million. Currently, however, accurate data collection in the non-critical care setting is still under development in Wales and it is thought that the real number will be far higher. Sepsis is a major cause of avoidable deaths and it is essential that to understand the size of the problem within Wales so that the quality of care that patients receive can be improved. There has been a change in the definition of sepsis and it is unclear how this change will affect the detection and treatment of the condition in the UK healthcare setting. The aim of this study is to look at the prevalence (commonness) of sepsis across acute hospitals (hospitals with an emergency department) across Wales using the currently used and new definitions of sepsis.

Who can participate?
Adults with suspected sepsis who have been admitted to an emergency department or general ward at participating hospitals in Wales.

What does the study involve?
Over a 24 hour period, study staff monitor the number of adults who are admitted to one of the participating acute hospitals with suspected sepsis. The patients who have sepsis confirmed are asked to complete a very short questionnaire to measure their quality of life 1 year after they are discharged from the hospital. Ninety days after the start of the study, all participants have their medical notes reviewed by the study team in order to find out the number of deaths. The patient's details will be linked to the Secure Anonymised Information Linkage Databank (http://www.saildatabank.com) so the study team can follow them up looking at their healthcare use and long-term outcome.

What are the possible benefits and risks of participating?
There are no direct benefits or risks to participants taking part in this study.

Where is the study run from?
Fifteen acute hospitals in Wales (UK)

When is the study starting and how long is it expected to run for?
February 2016 to January 2020

Who is funding the study?
UK Sepsis Trust (UK)

Who is the main contact?
Dr Tamas Szakmany

Contact information

Type(s)
Public

Contact name
Dr Tamas Szakmany

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0

Study information

Scientific Title
DEfining SEPsis on The Wards: point prevalence study

Acronym
DESEPTiW

Study objectives
The 2012 definitions described sepsis as confirmed or suspected infection together with 2 or more clinical criteria present. The 3rd International Consensus Definitions for sepsis describe the condition as life-threatening organ dysfunction caused by a dysregulated host response to infection. The aim of this study is to look at the prevalence (commonness) of sepsis across acute hospitals (hospitals with an emergency department) across Wales using the currently used and new definitions of sepsis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales 3 REC

Study design
Prospective observational one-day point-prevalence study with longitudinal follow-up

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
See additional files

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

Interventions
To define acute deterioration we will take a pragmatic approach and look at increase in the NEWS score within the preceding 24-hour period. We will look at the time of the worst NEWS score and use those observations and investigations closest to this time to determine the SOFA score.

The NEWS (National Early Warning) Score is a universal track and trigger scoring system used in Wales to identify acutely unwell patients in the hospital. The SOFA (Sequential Organ Failure Assessment score) is used to identify critically unwell patients on the Intensive Care Units and hospital wards. Both scores are calculated from routine observations such as heart rate, blood pressure, respiratory rate and in case of the SOFA score some routinely obtained laboratory parameters such as white cell count.

Utilisation of sepsis screening tools and delivery of Sepsis 6 will also be assessed.

Hospital outcome data will be collected on the e-CRF (electronic case report) form and patient-level longitudinal outcomes including microbiology data will be collected via the linked SAIL database (a database of anonymised data about the population of Wales). Researchers will collect information on health care resource utilisation (number of GP visits, number and duration of hospital stay, number and nature of surgical procedures, number, duration and level of organ support during ICU stay) in the year preceding and two years after the study day. They will also link available microbiology data from the period of 14 days before and 90 days after the study day to assess the aetiology of the infection and determine any significant secondary infections.

Intervention Type
Other

Primary outcome measure
Prevalence of sepsis by both the 2012 Consensus definitions and the 3rd International Consensus Definitions. Measured on the day of the study in the Emergency Departments and general hospital wards.

Secondary outcome measures
1. Evaluation of the microbiology of sepsis linking the patient episode to the Public Health Wales /Public Health England microbiology database. Evaluated after 30 days of study entry.
2. Assessment of practice gaps in care of patients with sepsis by measuring compliance with the Sepsis 6 bundle.
3. To evaluate the impact of sepsis on patient outcome, particularly on long-term healthcare utilization (2 years post discharge) and quality of life (12 months post discharge) using linked healthcare data from the SAIL database. Mortality will be measured at 30, 90 days and 1 and 2 years following study entry. Quality of life will be assessed using the EQ-5D questionnaire during a telephone interview at 12 months.

Overall study start date
18/02/2016

Completion date
31/01/2020

Eligibility

Key inclusion criteria
For the study day (0800 to 0759), consecutive patients presenting to the emergency department (ED) and acute hospital wards with sepsis related admission and patients presenting to the emergency department (ED) and acute hospital wards with acute ongoing sepsis will be enrolled. To be eligible patients must have all of the following:
1. Must be admitted or transferred to either the ED or hospital ward or critical care area.
2. Have a NEWS (National Early Warning) score of 3 or above
3. Have a high clinical suspicion of an infection
4. Have sepsis as defined by:
4.1. Either as infection together with two or more SIRS criteria (2012 definition)
4.2. Or as suspected or documented infection AND a proxy for organ dysfunction (i.e. acute increase of ≥2 SOFA (Sequential Organ Failure Assessment) points)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
250

Total final enrolment
1651

Key exclusion criteria
1. Patients less than 18 years of age
2. Patients in acute Mental Health wards

Date of first enrolment
19/10/2016

Date of final enrolment
10/10/2019

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Glangwili General Hospital
Dolgwili Road
Carmarthen
United Kingdom
SA31 2AF

Study participating centre
Morriston Hospital
Heol Maes Eglwys Morriston
Swansea
United Kingdom
SA6 6NL

Study participating centre

Nevill Hall Hospital
Brecon Road
Abergavenny
United Kingdom
NP7 7EGA

Study participating centre
Prince Charles Hospital
Gurnos Road
Merthyr Tydfil
United Kingdom
CF47 9DT

Study participating centre
Princess of Wales Hospital
Coity Road
Bridgend
United Kingdom
CF31 1RQ

Study participating centre
Royal Glamorgan Hospital
Ynysmaerdy
Pntyclun
United Kingdom
CF72 8XR

Study participating centre
Royal Gwent Hospital
Cardiff Road
Newport
United Kingdom
NP20 2UB

Study participating centre
Withybush Hospital
Fishguard Road
Haverfordwest
United Kingdom
SA61 2PZ

Study participating centre
Wrexham Maelor Hospital
Croesnewydd Road
Wrexham
United Kingdom
LL13 7TD

Study participating centre
Ysbyty Gwynedd
Penrhosgarnedd
Bangor
United Kingdom
LL57 2PW

Study participating centre
Ysbyty Glan Clwydd
Rhuddlan Road Bodelwyddan
Rhyl
United Kingdom
LL18 5UJ

Sponsor information

Organisation
Aneurin Bevan University Health Board

Sponsor details
Research and Development Directorate
The Friars
Royal Gwent Hospital
Cardiff Road
Newport
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NP20 2UB

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/045gxp391

Funder(s)

Funder type
Charity

Funder Name
UK Sepsis Trust

Funder Name
Health and Care Research Wales

Results and Publications

Publication and dissemination plan
National and international conferences and publications.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		11/05/2016	23/06/2016	No	Yes
Results article	results	01/02/2018	12/06/2019	Yes	No
Results article	results	01/02/2018	12/06/2019	Yes	No
Results article	results	11/10/2018	12/06/2019	Yes	No
Results article	results	01/12/2018	12/06/2019	Yes	No
Results article	results	29/08/2019	13/03/2020	Yes	No
Results article	results	10/08/2021	12/08/2021	Yes	No
Other publications		21/10/2021	10/07/2023	Yes	No
Other publications		10/12/2021	10/07/2023	Yes	No