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Size of sepsis in Wales

Submission date	Recruitment status	[_] Prospectively registered
30/12/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/01/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/09/2017	Infections and Infestations	

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 recognized 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. The aim of this study is to look at the prevalence (commonness) of sepsis across acute hospitals (hospitals with an emergency department) across Wales.

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

What does the study involve?
Over a 24 hour period, study staff will 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 questionnaire to measure their quality of life 6 years after they are discharged from 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.

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?
Thirteen acute hospitals in Wales (UK)

When is the study starting and how long is it expected to run for?
June 2015 to February 2016

Who is funding the study?
1. Welsh Intensive Care Society (UK)
2. UK Sepsis Trust (UK)
3. Cwm Taf University Health Board (UK)

Who is the main contact?
Dr Tamas Szakmany

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3.1

Study information

Scientific Title
The size of sepsis in Wales: Point prevalence study of sepsis in the acute hospital

Study objectives
The aim of this study is to evaluate the prevalence of sepsis in acute hospitals in Wales.

Developing the digital data collection platform: http://www.ncbi.nlm.nih.gov/pubmed/27094989

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - Solihull, 07/04/2015, ref: 15/WM/0095

Study design
Prospective observational multi-centre cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

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

Interventions
The study will test the prevalence of sepsis on the general wards and Emergency Departments over a 24 hour period. Data will be collected using an electronic data collection tool on basic demographics, whether patients fulfil sepsis criteria according to the 2012 Consensus Conference definitions and whether Sepsis 6 has been delivered to the patients. Those patients who are screened positive for sepsis will be invited to fill out a validated health-related quality of life questionnaire (SF-36) 6 months following hospital discharge.

Intervention Type

Primary outcome measure
1. Prevalence of sepsis in the acute hospital setting is determined by reviewing patient notes on the study day (24 hours)
2. Mortality rate of sepsis is measured by reviewing patient notes at 90 days

Secondary outcome measures
1. Quality of life of sepsis survivors is determined using SF-36 questionnaire at 6 months
2. Completion and barriers of Sepsis 6 are determined by reviewing patient notes on the study day (24 hours)

Overall study start date
17/06/2015

Completion date
28/02/2016

Eligibility

Key inclusion criteria
1. Must be admitted or transferred to either the ED or hospital ward or critical care area
2. NEWS score of 3 or above
3. High clinical suspicion of an infection
4. Have sepsis as defined by an infection together with two or more SIRS criteria
5. Aged 18 years or over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
Aged less than 18 years

Date of first enrolment
17/06/2015

Date of final enrolment
18/06/2015

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
Prince Philip Hospital
Bryngwyn Mawr Dafen Road
Llanelli
United Kingdom
SA14 8QF

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
Singleton Hospital
Sketty Lane
Sketty
Swansea
United Kingdom
SA2 8QA

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
Cwm Taf University Health Board

Sponsor details
Ynysmeurig House Navigation Park
Abercynon
Wales
United Kingdom
CF45 4SN

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00rh52j13

Funder(s)

Funder type
Charity

Funder Name
Welsh Intensive Care Society

Funder Name
UK Sepsis Trust

Funder Name
Cwm Taf University Health Board

Results and Publications

Publication and dissemination plan
National and international conferences and publications.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2015		Yes	No
Results article	results	01/11/2016		Yes	No
Results article	results	01/12/2016		Yes	No
HRA research summary			28/06/2023	No	No