Size of sepsis in Wales

Submission date	Recruitment status No longer recruiting	Prospectively registered		
30/12/2015		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
26/01/2016	Completed	[X] Results		
Last Edited 25/09/2017	Condition category	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 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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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Screening

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(s)

- 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

Key secondary outcome(s))

- 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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes