ISRCTN78293101 https://doi.org/10.1186/ISRCTN78293101

# 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
Dr Tamas Szakmany

### ORCID ID
http://orcid.org/0000-0003-3632-8844

### Contact details
Department of Anaesthesia Intensive Care and Pain Medicine
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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 |