

Simulation of a clinical scenario of status epilepticus to investigate the adherence of the physician's response to treatment guidelines

Submission date 03/03/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/03/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/10/2019	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Status epilepticus (SE) is a life-threatening condition in which a person has a seizure (fit) lasting more than 5 minutes or repeated seizures within 5 minutes without returning to normal in between. It can result in death or long-lasting injury to the brain. SE can occur in people with epilepsy or in people who don't have epilepsy and can have a variety of causes. SE should be treated as an emergency and requires several assessments and treatments to be given quickly. The European and American Epilepsy Societies have published guidelines for the treatment of SE to encourage consistent high-quality treatment of SE. Most national guidelines are based on these guidelines. However, the quality of SE treatment and whether the guidelines are followed by doctors has not been tested in a standardized setting. The study will simulate an emergency where a person has SE from alcohol withdrawal and will test the doctor's decisions in how to investigate, treat and follow up the patient. The aim is to measure the quality of doctors' emergency first response to SE and to identify risk factors for not following treatment guidelines.

Who can participate?

Voluntary workshops will be offered to medical doctors working as resident physicians in the following four medical fields: intensive care medicine, emergency medicine, internal medicine and neurology at the University Hospital Basel.

What does the study involve?

All participants will receive an introduction to the simulator and the simulator room and how they work. Participants will perform the simulation one by one. Participants will be informed that the scenario is that they are the physician on call on an emergency unit and that a nurse will be available to support them. The nurse will be instructed to display a helpful manner but to act on the doctor's command only.

What are the benefits and risks of participating?

There are no anticipated risks, since the participants will only be taking part in a simulated emergency. Participants might benefit from the opportunity to practice an emergency scenario.

Where is the study run from?
University Hospital Basel (Switzerland)

When is the study starting and how long is it expected to run for?
June 2016 to July 2018

Who is funding the study?
University Hospital Basel (Switzerland)

Who is the main contact?
Dr Raoul Sutter (raoul.sutter@usb.ch)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol01/2017

Study information

Scientific Title
Emergency management of convulsive status epilepticus in a high-fidelity simulation: a prospective single-blinded study

Acronym

SESIM

Study objectives

We hypothesize that emergency response to patients with suspected status epilepticus does not strictly adhere to current international treatment guidelines.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval not required: this study is part of our quality assurance program

Study design

Prospective single-blinded observational study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

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

Health condition(s) or problem(s) studied

Status epilepticus

Interventions

All participating physicians will receive a standardized introduction of the technicalities of the simulator and the simulator room. Participating physicians will be asked if they would like to voluntarily be trained for clinical emergency scenarios. Upon their agreement, they will be informed that for the scenario they will be the physician on call on an emergency unit and that a nurse will be available to support them. The nurse will be instructed to display a helpful manner but to act on command only. The scenario will represent a patient admitted to the emergency room with convulsive status epilepticus induced by alcohol withdrawal.

Intervention Type

Behavioural

Primary outcome measure

1. Time to airway protection
2. Time to administration of supplementary oxygen

3. Time to administration of first- and second-line antiseizure drugs

All times are measured during simulation (i.e. time from start of simulated scenario to action /treatment).

Secondary outcome measures

1. Assessment of vital signs and neurologic status
 2. Ascertainment of medical history and laboratory results
 3. Performance of and time to assessment of treatment responsiveness
 4. Correct aftermath reporting of clinical characteristics, management aspects, diagnosis and etiology
 5. Subjective self-evaluation, including subjective stress level, quality of their performance, the performance of the nurse and certainty of diagnosis, assessed using a questionnaire
- Secondary outcomes 1-4 are assessed by analyses of the audio-video recordings by two independent investigators. In cases of disagreement or discrepancies, re-analysis of the recordings are performed to reach consensus.

Overall study start date

01/06/2016

Completion date

01/07/2018

Eligibility

Key inclusion criteria

Volunteering medical doctors working as resident physicians in different medical fields, including intensive care medicine, emergency medicine, internal medicine, and neurology

Participant type(s)

Health professional

Age group

Adult

Sex

Both

Target number of participants

50

Total final enrolment

58

Key exclusion criteria

Physicians already having participated in the same simulated clinical scenario

Date of first enrolment

01/01/2017

Date of final enrolment

01/07/2018

Locations

Countries of recruitment

Switzerland

Study participating centre

University Hospital Basel

Petersgraben 4

Basel

Switzerland

4031

Sponsor information

Organisation

University Hospital Basel

Sponsor details

Medical Intensive Care Units

Basel

Switzerland

4031

+41 61 265 25 25

stephan.marsch@usb.ch

Sponsor type

Hospital/treatment centre

Website

<https://www.unispital-basel.ch/ueber-uns/bereiche/medizin/kliniken-institute-abteilungen/intensivmedizin/lehre-forschung/>

ROR

<https://ror.org/04k51q396>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital Basel

Results and Publications

Publication and dissemination plan

We plan to publish our results in a peer-reviewed journal.

Intention to publish date

01/07/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality issues.

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	05/11/2019	10/10/2019	Yes	No