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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

Registration date
06/03/2019

Overall study status
Completed

Last Edited
10/10/2019

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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4031

Sponsor information

Organisation
University Hospital Basel

Sponsor details
Medical Intensive Care Units
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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