Resource use and outcome in intensive care units

Submission date	Recruitment status No longer recruiting	Prospectively registered		
26/01/2021		[X] Protocol		
Registration date	Overall study status	[X] Statistical analysis plan		
31/01/2021	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
16/08/2022	Other			

Plain English summary of protocol

Background and study aims

Intensive care prevents death and disability caused by critical illness and it consumes large amounts of health care resources. The severity of illness influences both the risk of death and the amount of resources needed to achieve survivors. Both the ability to achieve survivors and the resources needed to achieve survivors at a specific severity of illness may vary widely between intensive care units internationally and within a country. The aim of this study is to evaluate variation in resources needed and the ability achieve survivors in intensive care units over time, using methods that take into account the severity of illness in resource use and mortality. This study attempts to find factors possibly related to such variations, for example, structural and organizational characteristics of the intensive care units in Finland, Estonia, and Switzerland.

Who can participate?

Patients treated in participating intensive care units from 1/1/2008 - 31/12/2017

What does the study involve?

The study uses routinely collected information of severity of illness and resource use during admissions to intensive care units. The data has been collected as part of standard care in a registry and will be analyzed in fully anonymized form, i.e. so that no patients can be recognized based on the data available for the study.

What are the benefits and risks of participating?

None for the individual patients. Potential benefits for society and health care may help to better allocate health care resources in the future.

Where is the study run from?

The study is run from the Department of Intensive Care Medicine, Bern University Hospital and University of Bern, Bern, Switzerland.

When is the study starting and how long is it expected to run for? August 2017 to April 2021 Who is funding the study? Investigator initiated and funded

Who is the main contact?
Professor (Emeritus) Jukka Takala, jukka.takala@med.unibe.ch

Contact information

Type(s)

Scientific

Contact name

Prof Jukka Takala

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Variation in severity-adjusted resource utilization and outcome in intensive care units

Study objectives

This health economic study evaluates variation in resource use and mortality, both standardized for the severity of illness, in intensive care units over time, assesses factors related to the variation, and evaluates the cost structure and ICU organization in participating intensive units in Finland, Estonia, and Switzerland.

Ethics approval required

Old ethics approval format

Ethics approval(s)

According to the national regulations in Finland, Estonia, and Switzerland, no ethics committee approval is needed for health economic studies using anonymized data from existing health care registry. The study protocol, database contents and process of data management were approved by the National Institute of Health and Welfare, Finland (Decision THL/1524/5.05.00/2017 and THL/1173/05.00/2018)

Study design

Retrospective analysis

Primary study design

Observational

Secondary study design

Cost-benefit analysis

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not applicable (retrospective study)

Health condition(s) or problem(s) studied

Resource use and hospital outcome standardized for severity of illness in patients admitted to intensive care units

Interventions

Registry data from all admissions in 21 intensive care units from 2008-2017 will be used.

Severity of illness and resource use data, collected prospectively in a quality registry, are retrospectively analyzed for severity adjusted, standardized resource use ratio (SRUR) and standardized mortality ratio (SMR). The variation over time and association between SRUR and SMR and their association with predefined structural and organizational variables will be analyzed.

Intervention Type

Other

Primary outcome measure

Resource use is measured from the retrospectively collected records using:

- 1. Length of intensive care unit stay
- 2. Daily collected data on therapeutic interventions (TISS-score)
- 3. Severity of illness measured during the first 24 hrs of intensive unit stay
- 4. Mortality measured at hospital discharge

Secondary outcome measures

Characteristics of treatment centres measured from the retrospectively collected records using:

- 1. ICU-category (University, small/large non-University)
- 2. Cardiac surgery in hospital (yes/no)
- 3. Neurosurgery in hospital (yes/no)
- 4. Nurses/bed
- 5. Nurses/bed to physician/bed ratio
- 6. Total number of beds
- 7. Readmissions/total admissions
- 8. Admissions/bed
- 9. Specialist availability 24/7 (yes/no)
- 10. Medical emergency team (yes/no)
- 11. Physician full time equivalents(FTE)/bed,
- 12. Organization type (independent or not)
- 13. Median SAPS category
- 14. SMR

Overall study start date

22/08/2017

Completion date

30/04/2021

Eligibility

Key inclusion criteria

All patients admitted to the participating intensive care units 2008-2017

Participant type(s)

Patient

Age group

All

Sex

Both

Target number of participants

207953

Total final enrolment

207953

Key exclusion criteria

- 1. Data collection error
- 2. Missing admission number
- 3. Missing severity score
- 4. Missing diagnosis

Date of first enrolment

01/01/2008

Date of final enrolment

31/12/2017

Locations

Countries of recruitment

Estonia

Finland

Switzerland

Study participating centre Bern University Hospital

Department of Intensive Care Medicine Inselspital Freiburgstrasse 18 Bern Switzerland 3010

Sponsor information

Organisation

University Hospital of Bern

Sponsor details

Department of Intensive Care Medicine Inselspital Freiburgstrasse 18 Bern Switzerland 3010 +41 316323938 kim.backoffice@insel.ch

Sponsor type

Hospital/treatment centre

Website

http://www.insel.ch/en/

ROR

https://ror.org/01q9sj412

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/01/2022

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan		29/01/2021	03/02/2021	No	No
Results article		18/10/2021	19/10/2021	Yes	No
<u>Protocol file</u>		22/08/2017	16/08/2022	No	No