ISRCTN10188560 https://doi.org/10.1186/ISRCTN10188560

Effectiveness of a collegial consultation procedure to improve in-patient care - a pragmatic cluster randomized controlled trial

Submission date
16/11/2017

Recruitment status
No longer recruiting

Registration date
18/05/2018

Overall study status
Completed

Last Edited
26/07/2022

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Particularly in the course of life-threatening illnesses (e.g. stroke, myocardial infarction, chronic obstructive pulmonary disease) longer ventilation can be necessary. Generally the duration and the amount of ventilation hours has been increasing. With increasing patient age the duration of ventilation procedures rises as well. The aim is to find and prevent potential errors and improve in-hospital quality regarding this high-risk procedure. Due to the association between ventilation, life-threatening illnesses and age of patients there is a risk of a high patient mortality (death rate) while performing ventilation for over 24 hours. The aim of this study is to find out whether the mortality of patients who were ventilated for over 24 hours improves due to an organized collegial consultation ("Peer-Review").

Who can participate?
Hospitals in Germany that are members of the Association Initiative Quality in Medicine and that treated 10 patients in 2016 who were ventilated for over 24 hours

What does the study involve?
Hospitals with the highest in-hospital deaths of patients who were ventilated for over 24 hours are randomly allocated into two groups. The intervention group gets a standardized peer review about ventilation from educated peers from a different hospital in the IQM network. The control group does not get a peer review. Participating hospitals that are not categorized to the highest in-hospital mortality of ventilated patients are allocated to observation only. The in-hospital mortality of patients who receive ventilation for over 24 hours is compared between the groups one year before and one year after the peer-review procedure.

What are the possible benefits and risks of participating?
Benefits include a possible reduction of in-hospital death rates due to better quality of care for the high-risk group of ventilated patients.

Where is the study run from?
Center for Evidence-based Healthcare (Germany)

When is the study starting and how long is it expected to run for?
January 2017 to September 2019 (updated 13/07/2020, previously: June 2019)

Who is funding the study?
Innovation fund of the Joint Federal Committee (Germany)

Who is the main contact?
Mr Felix Walther
felix.walther@ukdd.de

Contact information

Type(s)
Public

Contact name
Mr Felix Walther

Contact details
Center for evidence-based healthcare
Fetscherstraße 74
Dresden
Germany
01307
+49 (0)351 4581 9710
felix.walther@ukdd.de

Additional identifiers

Protocol serial number
01VSF16013

Study information

Scientific Title
Effectiveness of the “IQM”-Peer-Review-Procedure to improve in-patient outcome-quality - a pragmatic cluster-randomized controlled trial (IMPRESS)

Acronym
IMPRESS

Study objectives
The IMPRESS Study evaluates a complex quality-intervention on the basis of a cluster-randomized controlled trial. This trial primarily aims to investigate if outcome-quality (mortality) improves due to a (IQM)-peer-review procedure. The “Association Initiative Quality in Medicine” (IQM) is a non-profit-organization with optional membership of German or Swiss acute care hospitals. IQM is an interhospital community which serves as the basis for communication and improvement of inpatient-healthcare quality. The IQM-peer-review-intervention is a standardized, structured collegial case-discussion and consultation of specially trained

healthcare professionals. The goal of this intervention is to identify and eradicate error-potentials in structure and/or processes of care and to eventually improve in-house-quality. Observational studies suggest effectiveness of the peer review procedure, but controlled investigations are missing.

Hypothesis: The IQM-Peer-Review Procedure, a standardized collegial consultation procedure, improves in-patient care and decreases in-patient mortality of patients ventilated >24h.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee TU Dresden; registered at institutional review board (IRB): Office for Human Research Protections (OHRP); identification numbers: IRB00001473 and IORG0001076; Date of approval: 24/04/2017

Primary study design
Interventional

Study design
Cluster randomised controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Primary: ventilation >24h
Secondary: stroke, heart attack, COPD, pneumonia, colorectal resection

Interventions
The IMPRESS study is a two-armed cluster-randomized controlled intervention trial embedded in a prospective hospital-cohort study. 385 IQM-member-hospitals from Germany are invited to participate. 60 hospitals with the highest in-hospital-mortality of patients who were ventilated >24h are randomized into equally sized intervention group (receiving peer review consultation) and control group (standard care). The randomization procedure followed a block-randomization with a constant block-length of 10 clinics per block. The study coordination of the Center for evidence-based healthcare, TU Dresden developed the randomization list. To build balanced groups the participating hospitals will be stratified according to the number of patients/year (median-split) and hospital ownership (public, private, non-profit, university hospital).

Within 4 months after randomization the intervention group gets one standardized peer-review (intervention) regarding ventilation structures and processes through educated peers from a different hospital in the IQM network between the 06/01/2017 and 12/31/2017. The control group will not get any peer-review intervention regarding ventilation procedures between the 06 /01/2017 and 12/31/2017. Participating hospitals which are not categorized to the highest in-hospital mortality of patients who were ventilated >24h will not be randomized and will be assigned to the observation group.

To secure high data quality and safety the data-processing and data-analyzing sites are separated. The data analysts are blinded/masked to the allocated group of hospitals. Two analyses are planned. First, in the confirmatory analysis the primary outcome will be evaluated.

Second, the explorative analysis will evaluate the secondary outcomes. Every participating hospital of intervention, control or observational group will be analyzed for the years 2016, 2017 and 2018.

Intervention Type
Other

Primary outcome(s)
Age- and sex-adjusted mean inpatient mortality rate of hospitals in the intervention or control group within one year before (baseline) and one year follow-up after the peer-review procedure (post-intervention). The primary outcome is measured for patients who receive ventilation >24h

Key secondary outcome(s)
Age- and sex-adjusted mean inpatient mortality rate of every participating hospital regardless of observation, intervention or control group in 2016, 2017 and 2018. The secondary outcome is measured for patients who receive ventilation >24h and colorectal resection or patients with myocardial infarction, stroke, COPD and pneumonia, respectively. For all analyses the unit of analysis is the hospital, not the individual patient.

Completion date
30/09/2019

Eligibility

Key inclusion criteria
Hospital:
1. Member of the Association Initiative Quality in Medicine
2. Located in Germany
3. Treating 10 patients in 2016 who were ventilated > 24h
4. Consented into the study in the written form

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/2017

Date of final enrolment

01/04/2017

Locations

Countries of recruitment
Germany

Study participating centre
Center for Evidence-based Healthcare
Fetscherstraße 74
Dresden
Germany
01307

Sponsor information

Organisation
German Research Centre for Air and Space Travel (DLR)

ROR
https://ror.org/04bwf3e34

Funder(s)

Funder type
Government

Funder Name
Innovation fund of the Joint Federal Committee

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. The transfer and use of hospital-accounting data of every hospital underlies the German medical data protection laws due to a patient-relevance and an anonymization and its transfer is strictly bounded to the use of the IMPRESS study due to the patient-relevant details and is guaranteed in the participant (hospital) information sheet. This highly sensitive data is

held in a separate position/ organization of trust which will aggregate and anonymize the data. After this process the Center for Evidence-based healthcare will get the data for the realization of the confirmatory and exploratory analysis.

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		25/07/2022	26/07/2022	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes