Trial Description

Title

Investigation of the validity and improvement of the utility of claims data for quality improvement of treatment of sepsis in hospitals

Trial Acronym

OPTIMISE

URL of the trial

https://innovationsfonds.g-ba.de/projekte/versorgungsforschung/optimise-validierung-und-optimierung-der-nutzbarkeit-von-routinedaten-zur-qualitaetsverbesserung-des-sepsis-managements-im-krankenhaus.152

Brief Summary in Lay Language

Sepsis is the most common cause of preventable deaths in hospitals. The WHO, patient representatives as well as medical societies demand the improvement of quality of sepsis care. Routine data are getting more relevant for estimating incidence and burden of disease as well as for measuring the quality of care. Currently, there is no sufficient knowledge about how valid information based on routine data are for quality management of sepsis care. This study therefore aims to investigate how good sepsis and sepsis-related hospital mortality are represented in routine data.
Routine data in form of claims data are used for this study. These data are gathered by every German hospital offering inpatient care. Ten hospitals take part in the study and provide their claims data, of which 1000 cases per hospital are analyzed in depth. Patient records of these 10,000 cases will be screened by trained physicians. Physicians will judge the patient records for presence of sepsis. These judgements will be compared with the information on presence of sepsis in claims data. Also it will be investigated, if risk-factors for sepsis-related mortality are correctly represented in claims data. The results will be discussed with experts. Based on these discussions, recommendations will be made on how the utility of routine data for quality management of sepsis care can be improved.

Brief Summary in Scientific Language

Background
Sepsis is the most common cause of preventable deaths in hospitals. The WHO, patient representatives as well as medical societies demand the improvement of quality of sepsis care. Routine data are getting more relevant for estimating incidence and burden of disease as well as for measuring the quality of care. Currently, there is no sufficient knowledge about how valid information based on routine data are for quality management of sepsis care. This study therefore aims to investigate how good sepsis and sepsis-related hospital mortality are represented in routine data. The results of the study can be used to enhance the utility of routine date for the quality management of sepsis care. Additionally, based on the study results corrected estimates of sepsis incidence in Germany can be calculated using national routine data bases.

Method
Design: This is a multi-center retrospective observational study using routine data. No patients are recruited, the need for informed consent was waived. Based on claims data of the participating study centers a stratified sample of cases is obtained. For these cases patient records are systematically screened for sepsis by trained study physicians (true sepsis cases referred to as “gold standard”). The validity of ICD-coding of sepsis in claims data is estimated compared to this gold standard. Additionally, several methods for identification of sepsis in claims data presented in the research literature are also investigated regarding their validity (e.g. the implicit method that uses the combination of codes for infections and codes for organ dysfunctions to identify sepsis). The results of the study are discussed in an expert panel to make recommendations for enhancing the utility of claims data for quality management of sepsis care.

Sample: Ten hospitals take part. From the total of inpatient cases treated between 2015 and 2017, with age of at least 15 years, and billing based on the DRG-system a stratified sample of N=1200 cases per hospital is drawn. Patient records are screened in random order. The aim is to analyze at least 1000 records per study center (200 more are drawn to adjust for possibly missing records).

Procedure: Claims data are provided in pseudonymized form by the study centers. Study physicians are trained to identify sepsis using 40 training records. Another 40 records are used to estimate the objectivity of the sepsis identification by calculating inter-rater reliability of two independent study physicians. All available information of patient records is used to identify cases with sepsis among the 1000 study cases. Sepsis cases are identified based on current sepsis definitions (“sepsis-1”) as well as newly proposes definitions (“sepsis-3”). Study nurses document additional information for cases with sepsis (e. g. information on microbiology, risk-factors for mortality, course of treatment). Data are fed into an electronic case report form (eCRF). These data are linked with the information from claims data by a pseudonym.

Planned analyses: Proportions of sepsis based on sepsis-1 and sepsis-3 definition as well as proportions of subgroups (with and without organ dysfunction, septic shock) are calculated. Validity of the ICD-coding of sepsis in claims data is estimated by calculating sensitivity, specificity, positive and negative predictive value regarding the gold standard. In the same way the validity of the different methods for identification of cases with sepsis in claims data is calculated. Validity of risk-factors identified in claims data for sepsis-related mortality is also estimated in regard to these risk-factors identified form patient records. Risk-models for sepsis-related mortality are calculated based on information from claims data and based on information from patient records and are compared with each other regarding model fit and predicted mortality.

Organizational Data

- DRKS-ID: **DRKS00017775**
- Date of Registration in DRKS: **2019/10/14**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2018-1065-Daten , Ethikkommission der Friedrich-Schiller-Universität Jena an der Medizinischen Fakultät**

Secondary IDs

Health condition or Problem studied

- Free text: **Sepsis according to old sepsis-definitions (sepsis-1)**
- Free text: **Sepsis according to new sepsis-definitions ("sepsis-3")**
- ICD10: **A02.1 - Salmonella sepsis**
- ICD10: **A20.0 - Bubonic plague**
- ICD10: **A20.7 - Septicaemic plague**
- ICD10: **A21.7 - Generalized tularaemia**
- ICD10: **A22.7 - Anthrax sepsis**
- ICD10: **A24.1 - Acute and fulminating melioidosis**
- ICD10: **A26.7 - Erysipelothrix sepsis**
- ICD10: **A28.2 - Extraintestinal yersiniosis**
- ICD10: **A32.7 - Listerial sepsis**
- ICD10: **A39.1 - Waterhouse-Friderichsen syndrome**
- ICD10: **A39.2 - Acute meningococcaemia**
- ICD10: **A39.3 - Chronic meningococcaemia**
- ICD10: **A39.4 - Meningococcaemia, unspecified**
- ICD10: **A40 - Streptococcal sepsis**
- ICD10: **A41 - Other sepsis**
- ICD10: **A42.7 - Actinomycotic sepsis**
- ICD10: **A48.3 - Toxic shock syndrome**
- ICD10: **A49.9 - Bacterial infection, unspecified**
- ICD10: **A54.8 - Other gonococcal infections**
- ICD10: **B00.7 - Disseminated herpesviral disease**
- ICD10: **B37.6 - Candidal endocarditis**
- ICD10: **B37.7 - Candidal sepsis**
- ICD10: **B49 - Unspecified mycosis**
- ICD10: **O75.3 - Other infection during labour**
- ICD10: **O85 - Puerperal sepsis**
- ICD10: **P36 - Bacterial sepsis of newborn**
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ICD10: **R65.0 - Systemic Inflammatory Response Syndrome of infectious origin without organ failure**

- ICD10: **R65.1 - Systemic Inflammatory Response Syndrome of infectious origin with organ failure**
- ICD10: **R57.2 - Septic shock**

Interventions/Observational Groups

- Arm 1: **Based on claims data, a stratified sample of 1200 cases per study center is drawn from the population of inpatient cases with billing based on DRG, and age of at least 15 years. The strata are defined by the cross tabulation of a) presence of a procedure code for a complex critical care treatment, b) hospital length of stay up to or longer than 6 days, and c) year of hospital discharge. An equal number of cases per stratum is drawn.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Health care system**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Estimation of the validity (sensitivity, specificity, positive and negative predicitve value) of ICD-coding of sepsis with organ dysfunction including septic shock in German hospital claims data.

Secondary Outcome

a) Proportion of sepsis (without organ dysfunction, with organ dysfunction, septic shock) based on old sepsis-definitions (sepsis-1)
b) Proportion of sepsis (sepsis, septic shock) based on new sepsis-definitions (sepsis-3)
c) Validity (sensitivity, specificity, positive and negative predictive value) of different methods to identify sepsis based on ICD-codes and German procedure (OPS) codes
d) Validity (sensitivity, specificity, positive and negative predictive value) mortality risk-factors identified in claims data

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätsklinikum Jena, Jena**
- University Medical Center **Universitätsklinikum Gießen und Marburg GmbH: Standort Gießen, Gießen**
- University Medical Center **Universitätsmedizin Greifswald, Greifswald**
- University Medical Center **Klinikum rechts der Isar der Technischen Universität München, München**
- Medical Center **Klinikum Lippe GmbH: Standort Detmold, Detmold**
- University Medical Center **Universitätsklinikum Augsburg, Augsburg**
- University Medical Center **Universitätsklinikum Bonn, Bonn**
- University Medical Center **Charité Universitätsmedizin Berlin, Berlin**
- University Medical Center **Universitätsklinikum Frankfurt, Frankfurt a.M.**
- Medical Center **SRH Waldklinikum Gera, Gera**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2019/12/01**
- Target Sample Size: **10000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **15 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Billing based on DRG, inpatient cases, age of at least 15 years, discharge from hospital in years 2015-2017

Exclusion criteria

none

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting planned**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum der federführenden Ethikkommission**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*