Trial Description

Title

Ambulatory screening and decontamination to prevent STaphylococcus AUreus complications in patients with elective surgery

Trial Acronym

STAUfrei

URL of the trial

http://www.staufrei-hdh.de

Brief Summary in Lay Language

The STAUfrei Study investigates a possibility to reduce the number of certain harmful pathogens (Staphylococcus Aureus: MRSA and MSSA) in the hospital setting. This project is supported by the federal joint committee's innovation fund. During a hospital stay there is an elevated risk of complications due to wound infections after surgical interventions. This can result in prolonged hospital stays and increased use of antibiotics as well as additional GP visits.

The aim of the STAUfrei-Study is to prevent the introduction of S Aureus to the hospital setting. Before undergoing elective surgery, all patients will be screened by their GPs. In case of a positive results, patients will be decontaminated in the ambulatory setting. After completed surgery, patients will receive a follow-up treatment by their GP. This will include wound inspection as well as MRSA Screening and if necessary repeated decontamination.

Additional study objectives are i.a. health economic evaluation, prevention of surgical site infections and patient and provider satisfaction with the intervention.

Patients with a scheduled surgery in the Hospital in Heidenheim and aged 18 and above can take part in the study.

The study will be carried out in the district of Heidenheim. All patients with an elective surgery in the municipal hospital (Klinikum Heidenheim) are eligible for inclusion. The study will be carried out over a 3-year period, starting in April 2019.

Brief Summary in Scientific Language

The primary aim of the STAUfrei-Study is to prevent the introduction of S Aureus (MRSA and MSSA) to the hospital setting through systematic screening and decontamination prior to hospital admission. To reach this aim we will conduct a interventional study with a controlled before and after comparison with patients scheduled for elective surgery in the municipality hospital in Heidenheim. The new treatment model will encompass a ambulatory screeing prior to hospital admission as well as a structured after care in the ambulatory setting. Primary endpoint is the reduction of MRSA and MSSA colonizations upon hosptial admission. Secondary endpoints evaluate post operative complication rates (i.e. surgical site infections) as well as number of recolonizations. In addition acceptance and

satisfaction of providers (GPs and their medical team) and patients will be evaluated.
The intervetion phase will be conducted from April 2019 until March 2021.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00016615**
- Date of Registration in DRKS: **2019/04/01**
- 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.: **F-2018-090 , Ethik-Kommission bei der Landesärztekammer Baden-Württemberg**

Secondary IDs

Health condition or Problem studied

- Free text: **MRSA and MSSA colonization upon hospital admission**

Interventions/Observational Groups

- Arm 1: **Patients colonized with S Aureus will be instructed by their GPs to self-administer a comprehensive set of decontamination measures over a 5 day period prior to admission:**

  anitbacterial wash lotion (daily)
  nasal mupirocin ointment (3x per day)
  antiseptic mouth rinse (3x per day)
  desinfection of commonly used objects and aids as well as the environment (daily)
- Arm 2: **Routine care (SOP), usually 1-2 showers with an antiseptic soap prior to surgery**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Colonisation with MRSA and MSSA upon hospital admission

Secondary Outcome

Infection rates, post-operative MRSA colonization, incremental costs (ambulatory and hospital costs), Patient satisfaction (paper based questionnaire), Acceptance by providers (GPs and their teams)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Kliniken Landkreis Heidenheim gGmbH, Heidenheim**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/04/01**
- Target Sample Size: **13260**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Patients scheduled for elective surgery as well as risk bearing interventions in the hospital in Heidenheim (Klinikum Heidenheim)

Exclusion criteria

Patients below 18 years old and emergency patients

Addresses

- **Primary Sponsor**

  Der Innovationsfonds und der Innovationsausschuss beim Gemeinsamen Bundesausschuss
  Postfach 120606
  10623 Berlin
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **https://innovationsfonds.g-ba.de/**
- **Contact for Scientific Queries**

  Institut für Allgemeinmedizin und Interprofessionelle Versorgung (IAIV), Universitätsklinikum Tübingen
  Ms. Dr. med. Heidrun Sturm (MPH, Ph.D.)
  Osianderstraße 5
  72076 Tübingen
  Germany

  Telephone: **070712985269**
  Fax: **[---]***
  E-mail: **Heidrun.Sturm at med.uni-tuebingen.de**
  URL: **[---]***
- **Contact for Public Queries**

  STAUfrei-Zentrale Klinikum Heidenheim
  Ms. Elfriede Zeck
  Schloßhaustraße 100
  89522 Heidenheim an der Brenz
  Germany

Contact for Public Queries

STAUfrei-Zentrale Klinikum Heidenheim
Ms. Elfriede Zeck
Schloßhaustraße 100
89522 Heidenheim an der Brenz
Germany

Telephone: **07321 33 93050**
Fax: **[---]***
E-mail: **staufrei.sz at kliniken-heidenheim.de**
URL: **[---]***

■ **Collaborator, Other Address**

AOK Baden-Wuerttemberg
Ms. Mareen Reinhart
Presselstraße 19
70191 Stuttgart
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Collaborator, Other Address**

BKK Landesverband Süd
Mr. Stephan Trabert
Stuttgarterstraße 105
70806 Kornwestheim
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Collaborator, Other Address**

Steinbeis-Hochschule Berlin
Mr. Prof. Dr. med. Bernd Brüggenjürgen
Gürtelstraße 29A/30
10247 Berlin
Germany

Telephone: **[---]***
Fax: **[---]***

Collaborator, Other Address

Steinbeis-Hochschule Berlin
Mr. Prof. Dr. med. Bernd Brüggenjürgen
Gürtelstraße 29A/30
10247 Berlin
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Collaborator, Other Address**

Institut für Mikrobiologie und Hygiene, Universitätsklinikum Tübingen
Mr. Dr. Jan Liese
Silcherstraße 5
72076 Tübingen
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Collaborator, Other Address**

Landratsam Heidenheim, Fachbereich Gesundheit
Mr. Christoph Bauer
Felsentraße 36
89518 Heidenheim
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Collaborator, Other Address**

Institut für Allgemeinmedizin und Interprofessionelle Versorgung (IAIV), Univeristätsklinikum Tübingen
Ms. Prof. Dr. med. Stefanie Joos
Osianderstraße 5
72076 Tübingen
Germany

Telephone: **[---]***

Collaborator, Other Address

Institut für Allgemeinmedizin und Interprofessionelle Versorgung (IAIV), Univeristätsklinikum Tübingen
Ms. Prof. Dr. med. Stefanie Joos
Osianderstraße 5
72076 Tübingen
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Collaborator, Other Address**

Pathways Public Health GmbH
Ms. Rieke Schulz
Neustädtische Kirchstraße 8
10117 Berlin
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Collaborator, Other Address**

Institut für Klinische Epidemiologie und Angewandte Biometrie (IkEaB)
Mr. Prof. Dr. Peter Martus
Silcherstraße 5
72076 Tübingen
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Collaborator, Other Address**

Kassenärztliche Vereinigung Baden-Württemberg (KVBW)
Mr. Rüdiger Kucher
Albstadtweg 11
70567 Stuttgart
Germany

Telephone: **[---]***

Collaborator, Other Address

Kassenärztliche Vereinigung Baden-Württemberg (KVBW)
Mr. Rüdiger Kucher
Albstadtweg 11
70567 Stuttgart
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

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.)**

Innovationsausschuss beim Gemeinsamen Bundesausschuss
Postfch 120606
10623 Berlin
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

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

Trial Publications, Results and other documents

** 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.*