

Trial Description

Title

Epidemiology of MRSA in HCW in acute care facilities in comparison to the epidemiology of MRSA in HCW in long-term care facilities

Trial Acronym

EMP

URL of the trial

[---]*

Brief Summary in Lay Language

About one third of the general population is colonized by Staphylococcus aureus, a normally harmless bacterium. This microorganism is able to obtain several resistance genes to antibiotics; this fact may complicate the treatment of infections. Health care workers (physicians, nurses, emergency medical service) are at higher risk than the general public. We will determinate the frequency of the colonization in this study, we will plan to include 2100 subjects. We provided an amendment regarding an increase of subjects up to 3000 to ethics committee Greifswald on 23 June 2014, in order to assure a higher reliability of the data. MRSA-positive health care workers get an eradication cycle.

Brief Summary in Scientific Language

Staphylococcus aureus (SA) is a gram-positive bacterium colonizing skin and nares of circa one third of the general population. Infections are even possible, like folliculitis, severe septic or toxin-mediated complications. The increased usage of antibiotics exerts an additional selection pressure on SA causing resistance to certain antibiotics, especially resistance to β -lactamase antibiotics. Such a variant is called methicillin-resistant SA (MRSA). Nowadays, the term multi-resistant SA is more appropriate because of the acquisition of further resistance genes. Health care workers (HCW) are at higher risk than the general public during their operational function. We will determinate the frequency of the colonization of HCWs and we will plan to include 2100 subjects. We provided an amendment regarding an increase of subjects up to 3000 to ethics committee Greifswald on 23 June 2014, in order to assure a higher reliability of the data.

Organizational Data

- DRKS-ID: **DRKS00004603**
- Date of Registration in DRKS: **2013/01/03**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
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Ethics Approval/Approval of the Ethics Committee: **Approved**

- (leading) Ethics Committee Nr.: **BB111/12 , Ethikkommission an der Medizinischen Fakultät der Ernst-Moritz-Arndt-Universität Greifswald**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1137-8649**

Health condition or Problem studied

- ICD10: **U80.0 - Penicillin resistant agent**

Interventions/Observational Groups

- Arm 1: **detection of MRSA carriership, positive HCWs gain an eradication cycle**

Characteristics

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

Primary Outcome

Prevalence of MRSA in several groups of HCWs



Secondary Outcome

Rate of successful eradication, clonal patterns

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Universitätsmedizin Greifswald, Institut für Hygiene und Umweltmedizin, Greifswald**
- Medical Center **Klinik Grimmen, Bartmannshagen**
- Medical Center **Klinik Bad Doberan, Bad Doberan**
- Medical Center **Klinikum Ueckermünde, Ueckermünde**
- Medical Center **Klinikum Pasewalk, Pasewalk**
- Medical Center **Klinik Wolgast, Wolgast**
- other **Sozialzentrum "Am Grünhufer Bogen", Stralsund**
- other **Pflegeheim Ribnitz, Ribnitz-Damgarten**
- other **Pflegeheim "Haus am Bodden", Ribnitz-Damgarten**
- other **Curanum Seniorenpflegezentrum Barth, Barth**
- other **Diakonie Pflegeheim Göhren, Göhren**
- other **BDH-Klinik Greifswald, Greifswald**
- other **Medigreif Parkklinik, Greifswald**
- other **Rehaklinik Moorbad Bad Doberan, Bad Doberan**
- other **Reha-Zentrum Ückeritz, Ückeritz**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/05/14**
- Target Sample Size: **3000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**

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■ Minimum Age: **18 Years**

■ Maximum Age: **70 Years**

Additional Inclusion Criteria

Health care worker from 18 -65, informed consent

Exclusion criteria

no adequate comprehension of German, participation in another trial, intolerance to eradication medicine

Addresses

■ **Primary Sponsor**

**Institut für Hygiene und Umweltmedizin,
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■ **Contact for Scientific Queries**

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■ **Contact for Public Queries**

**Institut für Hygiene und Umweltmedizin
Universitätsmedizin Greifswald**

Contact for Public Queries

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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.)**

**Bundesministerium für Bildung und Forschung Dienstsitz Berlin
Friedrichstraße 130 B
10117 Berlin
Germany**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: **www.bmbf.de**

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

**Schülke & Mayr GmbH
Robert-Koch-Straße 2
22851 Norderstedt
Germany**

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E-mail: [---]*

URL: [---]*

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): [---]*

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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.*