Trial Description

Title

EFFECT of daily washing of patients with Octenidine impregnated wash-cloths on intensive care units on nosocomial infections – a randomised, double-blind, cross-over trial

Trial Acronym

EFFECT

URL of the trial

[---]*

Brief Summary in Lay Language

On intensive care units (ICU) patients will be washed on a daily basis. In the EFFECT-trial two washing methods are compared. Therefore, for 15 months, patients on the participating ICU patients will be washed with desinfectant impregnated wash-cloths or with wash-cloths that are not desinfectant.

After 15 months the other type of wash-cloths will be used. The order in which the different types of wash-cloths will be used, is determined by chance (randomisation).

Both types of wash-cloths are already used in the daily routine of ICUs.

Therefore, the trial recruits intensive care units as observation units and not single patients.

Brief Summary in Scientific Language

EFFECT wants to investigate, if washing with octenidine-impregnated wash-cloths (verum), compared to wash-cloths without active component (placebo), reduces the risk of proven nosokomial pathogens in a standard care setting.

EFFECT is a multicentre, controlled, cluster-randomized, double-blind, AB-BA-Cross-over study. The participating intensive care units are randomised in a cross-over manner to outhweigh period effects (secular trends).

The study intervention only consists of the use of disinfectant, with octenidine-impregnated wash-cloths for the daily routine bathing of patients, compared to using a wash-cloth without antiseptic.

Therefore, the trial recruits intensive care units as observation units and not single patients.

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

[---]*

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[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00011282**
- Date of Registration in DRKS: **2016/11/15**
- 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.: **340/16-ek , Ethikkommission an der Medizinischen Fakultät der Universität Leipzig**

Secondary IDs

Health condition or Problem studied

- Free text: **infection prevention on intensive care units**

Interventions/Observational Groups

- Arm 1: **1. daily bathing of all patients on the intensive care unit with octenidine-impregnated wash-cloths (15 months)**

  2. daily bathing of all patients on the intensive care unit with wash-cloths without antiseptic (15 months)
- Arm 2: **1. daily bathing of all patients on the intensive care unit with wash-cloths without antiseptic (15 months)**

  2. daily bathing of all patients on the intensive care unit with octenidine-impregnated wash-cloths (15 months)

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **investigator/therapist, caregiver, data analyst**
- Control: **Placebo**
- Purpose: **Prevention**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

co-primary endpoints:
1. multidrug-resistant organisms (MDRO) that are acquired on intensive care units and 2. primary bacteriaemia that are acquired on intensive care units

The endpoints are calculated with movement data in combination with the microbiological findings to generate intensive care unit episodes that will be rated on the basis of an algorithm.

The data will be transferred after each wash-out and each observation period respectively.

Secondary Outcome

to 1st co-primary endpoint:
1a) on Intensive care unit (ICU) acquired MRSA
1b) on ICU acquired VRE
1c) on ICU acquired MRGN

to 2nd co-primary endpoint:
2a) on ICU acquired primary bacteriaemia with pathogen
2b) on ICU acquired primary bacteriaemia with grampositive pathogen
2c) on ICU acquired primary bacteriaemia with gramnegative pathogen
2d) on ICU acquired primary bacteriaemia with common skin pathogen
2e) on ICU acquired primary or secondary bacteriaemia

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätsklinikum Leipzig, Leipzig**

- Medical Center **Klinikum Weiden, Weiden**
- Medical Center **Carl-Thiem-Klinikum, Cottbus**
- Medical Center **Krankenhaus Düren, Düren**
- University Medical Center **Klinikum Oldenburg, Oldenburg**
- Medical Center **Klinikum Braunschweig, Braunschweig**
- Medical Center **Klinikum Fulda, Fulda**
- Medical Center **Helios Klinikum Schwerin, Schwerin**
- Medical Center **Helios Klinikum Leezen, Leezen**
- University Medical Center **Universitätsklinikum Essen, Essen**
- University Medical Center **Universitätsklinikum Magdeburg, Magdeburg**
- Medical Center **Klinikum Chemnitz, Chemnitz**
- Medical Center **Klinikum Herford, Herford**
- Medical Center **Heinrich-Braun-Klinikum Zwickau, Zwickau**
- Medical Center **Klinikum Lippe, Detmold**
- Medical Center **Westküstenklinikum, Heide**
- Medical Center **Klinikum St. Georg, Leipzig**
- University Medical Center **Universitätsklinikum, Regensburg**
- Medical Center **Ubbo-Emmius-Klinik, Aurich**
- University Medical Center **Universitätsklinikum Düsseldorf, Düsseldorf**
- Medical Center **Lahn-Dill-Kliniken, Wetzlar**
- Medical Center **Marien Hospital Düsseldorf, Düsseldorf**
- Medical Center **Helios Klinikum Krefeld, Krefeld**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/01/01**
- Target Sample Size: **45**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **[---]***
- Minimum Age: **[---]* [---]***
- Maximum Age: **[---]* [---]***

Additional Inclusion Criteria

1. In general, (e.g. 90%), patients on the ICU are overall washed by nursing staff on a daily basis. ICUs, where a relevant part of the patients are entirely washing themselves or may not be washed, may not participate.
2. MRDO-Screening SOPs are in force
3. all individual and microbiological data can be made electronically available

Exclusion criteria

1. ICU with specialisation on burn patients, because in these patients a comprehensive washing is contraindicated.
2. ICU with specialisation on bone marrow transplants, because these patients are often mobile and wash themselves
3. paediatric ICUs, because the test product is only to be used after the age of 3.
4. Participation in other (investigative) projects that interfere with the endpoints of EFFECT (assessment by the coordinating investigator)
5. Restructuring activities on the ICU or in the hospital in the next 3 years. (assessment by the coordinating investigator)
Examples:
5a) planned major changes of patient groups
5b) planned change of MRDO screening procedures
5c) planned change of microbiological laboratory

Addresses

- **Primary Sponsor**

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- **Contact for Scientific 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.)**

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Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.dfg.de**

Status

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

Trial Publications, Results and other documents

- trial protocol (mandatory for transfer to Studybox) **EFFECT_Pruefplan_final2.0_2016-11-08.pdf**
- Paper **EFFECT-Studie Publikation des Studiendesigns**

** 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.*