

**PLEASE NOTE:** *This trial has been registered retrospectively.*

## Trial Description

### Title

**presurgical universal decolonisation in native Joint arthroplasty with polyhexanid**

### Trial Acronym

**PREVENTION**

### URL of the trial

[---]\*

### Brief Summary in Lay Language

[---]\*

### Brief Summary in Scientific Language

**The objective of this multicentric cohort study with a historic control is to test if introduction of a universal decolonisation of orthopaedic & traumatological patients receiving native Joint arthroplasty of the knee/hip or spondylodesis/surgery of the lumbar spine influences the rate of surgical site infection.**

**Patients that are meeting the inclusion criteria and are willing to participate will receive a set with with polyhexanid containing products (wipes, nasal gel, mouth wash), instructions and a questionnaire for evaluation prior to their planned surgery. They will be asked to use the provided set according to instructions 4 days prior to the scheduled surgery. Patients with surgery due to fracture of the femur, will receive two cycles of application.**

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

[---]\*

### Description IPD sharing plan

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00011505**
- Date of Registration in DRKS: **2017/02/15**
- 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.: **EA4/124/16 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

## Secondary IDs

## Health condition or Problem studied

- Free text: **Surgical site infections after primary total joint arthroplasty in native hip-/ knee joints or spondylodesis.**
- ICD10: **T81.4 - Infection following a procedure, not elsewhere classified**

## Interventions/Observational Groups

- Arm 1: **Intervention Group: Universal decolonisation of patients that meet the criteria with polyhenid containing washcloths, gel for intranasal application and mouthwash. Products should be used at least twice, but patients with elective surgery should start 4 days Prior to surgery.**
- Arm 2: **Control Group: historic cohort of patients that meet the inclusion and not the exclusion criteria. Those patients were surgically treated in the participating centers prior to indtroduction of the Quality improvement measure.**

## Characteristics

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

### Primary Outcome

**Rate of surgical site infections defined in the participating Centers in the german surveillance System for nosocomial infections/ KISS (CDC-definitions).**

### Secondary Outcome

**questionnaire evaluating Patient satisfaction and safety.**

### Countries of recruitment

- **DE Germany**

### Locations of Recruitment

- Medical Center **Evangelisches Waldkrankenhaus Spandau, Berlin**
- Medical Center **Martin Luther Krankenhaus , Berlin**
- Medical Center **Evangelische Elisabeth Klinik, Berlin**
- Medical Center **Evangelisches Krankenhaus Hubertus, Berlin**
- Medical Center **Oberlinklinik, Potsdam**
- Medical Center **Evangelisches Krankenhaus Paul Gerhardt Stift, Wittenberg**

### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/01/02**
- Target Sample Size: **4800**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

### Inclusion Criteria

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

### Additional Inclusion Criteria

**Indication for a native joint arthroplasty of the knee/ hip or a spondylodesis/surgery of the lumbar spine.**

## Exclusion criteria

**known allergy against polyhexanid or other substances that are present in the decolonisation products. Indication for surgery that is not a native joint arthroplasty of the knee/ hip or a spondylodesis/surgery of the lumbar spine.**

## Addresses

### ■ Primary Sponsor

**Charité Universitätsmedizin Berlin Institut für Hygiene und Umweltmedizin  
Ms. Univ. Prof. Dr. med. Petra Gastmeier  
Hindenburgdamm 27  
12203 Berlin  
Germany**

Telephone: **030/450-577912**

Fax: **030/450-577920**

E-mail: **prevention-studie at charite.de**

URL: [---]\*

### ■ Contact for Scientific Queries

**Charité Universitätsmedizin Berlin Institut für Hygiene und Umweltmedizin  
Mr. Dr. med., MSc Tobias Kramer  
Hindenburgdamm 27  
12203 Berlin  
Germany**

Telephone: **030/450-577612**

Fax: **030/450-577920**

E-mail: **prevention-studie at charite.de**

URL: **<https://hygiene.charite.de/>**

### ■ Contact for Public Queries

**Charité Universitätsmedizin Berlin Institut für Hygiene und Umweltmedizin  
Mr. Dr. med., MSc Tobias Kramer  
Hindenburgdamm 27  
12203 Berlin  
Germany**

Telephone: **030/450-577 912**

Fax: **030/450-577 920**

E-mail: **prevention-studie at charite.de**

URL: **<https://hygiene.charite.de/>**

## Sources of Monetary or Material Support

DRKS-ID: **DRKS00011505**

Date of Registration in DRKS: **2017/02/15**

Date of Registration in Partner Registry or other Primary Registry: [---]\*

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

**B. Braun Medical AGOM-ME-CH05**

**Seesatz 17**

**CH-6204 Sempach**

**Switzerland**

Telephone: **+41 58 258 50 00**

Fax: **+41 58 258 63 81**

E-mail: **info at bbraun.com**

URL: **www.bbraun.ch**

## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2018/12/01**

## 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.*