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# Web-based program for anti-infective treatment using evidence-based algorithms adapted to local resistance rates

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 17/08/2007 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 04/10/2007 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 22/07/2015 | Signs and Symptoms | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

## Study information

**Scientific Title**
Web-based program for anti-infective treatment using evidence-based algorithms adapted to local resistance rates

## Study objectives
Hypotheses of this study are: evidence-based anti-infective Standard Operating Procedures (SOPs), adapted to the local resistance rates and to the patient's special risk profile in computerised form:
1. Enhances the adherence rate to SOPs
2. Improves outcome:
2.1. Reduced organ dysfunction, Intensive Care Unit (ICU) stay and mortaliy rates
2.2. Reduces the resistance rates (local rates and national benchmarks)
2.3. Reduces the need (national benchmark) and costs for anti-infectives and the expense for isolation
2.4. Reduces the incidence of Post-Traumatic Stress Disorder (PTSD) after ICU stay (PTSD score)
2.5. Improves the perceived health related quality of life and cost-effectiveness

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Charite - Universitatsmedizin Berlin Ethics Committee, 06/09/2007, ref: EA1/127/07

## Primary study design
Observational

## Study design
Prospective observational study

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Critical illness

## Interventions
Intended duration: 36 months -
1. 12 months: conversion of the user-accepted SOPs into a web-based version for each participating centre including evidence-based medicine and local resistance rates
2. 12 months: assessment of the implementation rate before and after support by the user-accepted web based versions plus evaluation of the ICU stay and mortality rate with and without SOP adherence
3. 12 months: benchmarking between eight centres and ICU registered national databases for patient outcome and development of resistance rates. Assessment of Health-Related Quality of Life (HRQoL) and Quality-Adjusted Life Years (QALYs) for surviving patients after web-based SOP implementation

Follow up:
The entire duration of the trial is four years, starting January 2006 and ending December 2009.

## Intervention Type
Other

## Phase
Not Specified

### Primary outcome(s)
1. Implementation rate of SOPs before and after support of web-based computer program
2. Mortality rate with and without adherence to SOPs

Proof of the two primary endpoints in the sense of multiple testing with alpha/2 = 2.5% (Bonferroni's adjustment), i.e., with an error of the first kind of 2.5% each. A drop-out of 10% will be incorporated.

Ongoing outcome measurements in three months intervals including data collection and subsequent three months periods of data interpretation, comparison, and assessment.

### Key secondary outcome(s)
1. Infections with multi-resistant bacteria
2. Beginning and duration of anti-infective therapy
3. Length of infection induced organ failure (ventilator days, Sequential Organ Failure Assessment [SOFA] scores)
4. Duration of ICU treatment including rate of admissions to other ICUs
5. Length of ICU stay

Ongoing outcome measurements in three months intervals including data collection and subsequent three months periods of data interpretation, comparison, and assessment. An exploratory data analysis is planned for the assessment of the secondary outcome measures and risk factor analysis.

### Completion date
01/10/2010

## Eligibility

### Key inclusion criteria
All patients admitted to five ICUs at Universitaetsmedizin Charite at Campus Mitte and Campus Virchow-Klinikum

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. Patients under age of 18
2. Length of ICU stay less than 36 hours
3. Non-existing guideline for particular disease

**Date of first enrolment**
01/01/2006

**Date of final enrolment**
01/10/2010

# Locations

**Countries of recruitment**
Germany

**Study participating centre**
**Charite-Universitaetsmedizin Berin**
Berlin
Germany
13353

# Sponsor information

**Organisation**
Charite - University Medicine Berlin (Charite - Universitatsmedizin Berlin) (Germany)

**ROR**
https://ror.org/001w7jn25

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Charité Universitätsmedizin Berlin

**Alternative Name(s)**
Medical School - Charité - University Medicine Berlin

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
For-profit companies (industry)

**Location**
Germany

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 12/06/2014 | | Yes | No |
| Results article | results | 22/12/2014 | | Yes | No |