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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Prospective observational study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/01/2006

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

Age group
Adult

Sex
Both

Target number of participants
8000 participants

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)

Sponsor details

Campus Virchow-Klinikum
Augustenburger Platz 1
Berlin
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13383
-
claudia.spies@charite.de

Sponsor type
Hospital/treatment centre

Website
http://www.charite.de/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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