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Effects of digestive decontamination by amphotericine B on Candida colonisation and on the risk of invasive candidiasis in a surgical intensive care unit

Submission date 11/02/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/04/2009	**Overall study status** Completed	
Last Edited 20/04/2009	**Condition category** Infections and Infestations	

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

AFSSAPS ref: 021284

Study information

Scientific Title
Effects of digestive decontamination by amphotericine B on Candida colonisation and on the risk of invasive candidiasis in a surgical intensive care unit: a prospective randomised study

Acronym
DECONTAM

Study objectives
Interest of oral amphotericin B in prevention of candida contamination.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Hospital of Dijon (CHU Dijon), approved on 24/09/2002 (ref: 2002/18)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Candidiasis in intensive care unit

Interventions
Amphotericine B (oral) versus placebo.

Patients in group 1 received, from inclusion in the study, a measuring-spoonful of amphotericine B 10% (1 measuring spoonful = 15 ml), drinkable solution, three times a day along with a mouthwash with the same solution. Patients in group 2 received the placebo, conditioned the same way than amphotericine B, at the same moment and frequency. The treatment was continued during the hospitalisation. It was interrupted and replaced by a curative treatment of fluconazole for 21 days if the Candida colonisation index became higher than 0.5. The does of fluconazole was 800 mg intravenously (IV) on the first day and then 400 mg IV for 14 days or

longer (if colonisation persisted or candidemia appeared). This treatment was readjusted for the second time following the data of the antifungigram.

The patients were monitored during four weeks.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Amphotericin B

Primary outcome measure
Percentage of patients with Candida colonisation index (CI) >0.5, assessed weekly for 4 weeks.

Secondary outcome measures
Evaluation of fungal flora and candidemia, assessed weekly for 4 weeks.

Overall study start date
01/11/2002

Completion date
01/08/2003

Eligibility

Key inclusion criteria
1. Both males and females, no age limits
2. Patients hospitalised in a surgical intensive care unit with severe head trauma (Glasgow Coma Scale <8), heavy abdominal surgery or traumatic post-operative abdomen
3. Patients who have recently started a prolonged antibiotherapy
4. Long lasting hospitalisation in a intensive care unit
5. Screening candiduria above 10^4 colony forming units (cfu)/ml

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
40

Key exclusion criteria
Minor patients and patients for whom we had not collected their assent or of their family.

Date of first enrolment
01/11/2002

Date of final enrolment
01/08/2003

Locations

Countries of recruitment
France

Study participating centre
CHU de Dijon
Dijon
France
21033 Cedex

Sponsor information

Organisation
University Hospital of Dijon (CHU de Dijon) (France)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.chu-dijon.fr/

ROR
https://ror.org/0377z4z10

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital of Dijon (CHU de Dijon) (France)

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