

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
Registration date 20/04/2009	Overall study status Completed	☐ Protocol
Last Edited 20/04/2009	Condition category Infections and Infestations	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Nadine Milesi

Contact details

CHU de Dijon
3 Rue du Faubourg Raines
Dijon
France
21033 Cedex
nadine.milesi@chu-dijon.fr

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration