

Influence of symbiotics in the outcome of multiple organ dysfunction syndrome

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Registration date 16/01/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/01/2009	Condition category Other	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
FISCAM: PI-2007/13

Study information

Scientific Title
Influence of symbiotics in the outcome of multiple organ dysfunction syndrome: a prospective, aleatorised, randomised controlled trial

Study objectives

Bacterial translocation in the gastrointestinal tract is a key physiopathological process in the development of some critically ill patient's injuries, such as nosocomial pneumonia or multiple organ dysfunction syndrome. The bacterial overgrowth increases gut wall permeability, with associated bacterial translocation into the portal circulation leading to the development of distant septic foci. Different procedures have been used to eliminate the potentially pathogenic organisms for example: selective digestive decontamination with prophylactic administration of topic and intravenous antibiotic. An alternative approach is to introduce non-pathogenic bacteria which can replace the bacteria eliminated by antibiotic therapy and on the other hand, competitively inhibit colonisation by pathogenic strains.

Our working hypothesis is based on non-pathogenic bacteria from ICU-admission of the patient with at least two organ failures improving the course of patient-ICU, ICU-stay and hospital stay and could also have a beneficial effect on new individual organ failures. We think the administration of non-pathogenic bacteria will keep the normal flora in the gastrointestinal tract and decrease the multiple organ dysfunction syndrome incidence in ICU-patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Clinical Investigation Ethics Committee of Hospital "Virgen de la Salud" (Toledo, Spain) gave approval on 12th January 2008

Study design

Single-centre prospective aleatorised randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Multiple organ dysfunction syndrome

Interventions

Intervention group:

Priegola Simbiotic Drink®, a pasteurised milk, partially skimmed, with prebiotics (soluble fibre BENE0 1.5% [SYNERGY-1]) and probiotics (Streptococcus thermophilus, Lactobacillus bulgaricus, Lactobacillus casei, Lactobacillus acidophilus and Bifidobacterium). 100 ml every 12 hours, in the first twelve hours of the organ failures beginning (two or more), for a maximum of seven days.

Control group:

The control group will not receive the symbiotic.

The total duration of treatment in the interventional group will be a maximum of seven days from the organ failure beginning. If the patient is discharged from ICU before seven days (exitus, hospital room), the total number of days with symbiotics will be recorded. The total duration of follow-up for all arms will be for ICU-stay and the following will be recorded:

1. Days of ICU stay

2. Days of hospital stay
3. Mortality intra-ICU
4. Intra-hospital stay
5. Post-hospital discharge

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Priegola Simbiotic Drink®

Primary outcome(s)

1. Decrease in hospital stay: days of ICU stay and hospital stay will be assessed
2. Decrease of time and number of injured organs:
 - 2.1. Time of each organ failure and number of these will be assessed
 - 2.2. Sequential Organ Failure Assessment (SOFA) classification will be applied to define the dysfunction of each organ

Key secondary outcome(s)

1. Decrease of 30 day-mortality: assessed exitus (yes/no) inside UCI, post-hospital discharge and 30 days after hospital discharge
2. Decrease of the bloodstream infections, taking into account only the samples confirmed by the microbiology laboratory
3. Decrease of the nosocomial pneumonia, assessing the nosocomial pneumonia diagnosed by the attending clinician
4. Improvement of tolerance to enteral nutrition: the number of days the patient can feed with enteral nutrition only

Completion date

01/12/2009

Eligibility**Key inclusion criteria**

Adults (greater than 18 years, either sex) with two or more organ failures without exclusion criteria. The informed consent will be obtained from patients or their relatives.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Less than 18 years
2. Pregnant
3. Severe immunodepression (neutropenia less than 500/ml)
4. Inability to receive symbiotic administration
5. Pancreatitis
6. Symbiotics allergy
7. Death in the first 12 hours
8. Patients taking part in another clinical trial

Date of first enrolment

01/12/2008

Date of final enrolment

01/12/2009

Locations

Countries of recruitment

Spain

Study participating centre

Avda. Barber, 30

Toledo

Spain

45005

Sponsor information

Organisation

Hospital Virgen de la Salud (Spain)

ROR

<https://ror.org/0289cxp23>

Funder(s)

Funder type

Research organisation

Funder Name

FISCAM Health Research Foundation (Spain) (ref.: PI-2007/13)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration