ISRCTN22361317 https://doi.org/10.1186/ISRCTN22361317

Influence of symbiotics in the outcome of multiple organ dysfunction syndrome

Submission date 09/12/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 16/01/2009	**Overall study status** Completed	
Last Edited 16/01/2009	**Condition category** Other	

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 BENEO 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 measure
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

Secondary outcome measures
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

Overall study start date
01/12/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
175 patients by group (total: 350)

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
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Spain
45005

Sponsor information

Organisation
Hospital Virgen de la Salud (Spain)

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Sponsor type
Hospital/treatment centre

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

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