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Early enteral supply of Intestamin® in severe sepsis and its influence on organ dysfunction

Submission date	Recruitment status	[_] Prospectively registered
01/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/06/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/02/2010	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

Protocol serial number
N-IS1-10-UK

Study information

Scientific Title

Study objectives

To confirm that early enteral supply of Intestamin® to critically ill, septic patients results in a significantly faster reduction of daily total Sequential Organ Failure Assessment (SOFA) scores (organ dysfunction) during the first 5 treatment days compared to placebo (control supplement)

Ethics approval required
Old ethics approval format

Ethics approval(s)
St Thomas' Hospital Research Ethics Committee

Study design
Randomised, prospective, double-blind, placebo-controlled, monocentric, isoenergetic

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Sepsis

Interventions
Intestamin® versus placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Intestamin

Primary outcome(s)
Organ dysfunction assessed by daily total SOFA score and by the delta daily total SOFA score (significant reduction).
Variables for organ dysfunction (worst parameter per day):
1. Pulmonary: pO2/FiO2
2. Cardiovascular: hypotension
3. Renal: creatinine
4. Hepatic: bilirubin
5. Coagulation: thrombocytes
6. Central nervous system (CNS): Glasgow coma score

Key secondary outcome(s))
1. Mortality (28-day, ICU and hospital, six-months)
2. Infectious complications (e.g. pneumonia, wound infection, abscesses)
3. APACHE II
4. Organ failure-free days

5. LOS in ICU
6. LOS in hospital (intervention until discharge)
7. Duration of antibiotic treatment (antibiotics days)
8. Duration of ventilation (ventilator days)
9. Duration of renal support

Completion date
01/01/2008

Eligibility

Key inclusion criteria
Major entry criteria (suspected or proven infection, presence of a systemic response to the infection within the 48-hour period immediately preceding enrolment into the study, have or have had one or more sepsis-induced organ failures within the 48-hour period immediately preceding enrolment into the study).
1. Age ≥18 years
2. Acute Physiology and Chronic Health Evaluation II (APACHE II) score ≥10
3. Precipitating injury (surgery, trauma, hypovolemia, episode of infection or sepsis) occurred within the last 48 hours before intensive care unit (ICU) entry
4. Expected length of stay (LOS) in the ICU >3 days
5. Indication for enteral nutrition for 5-10 days
6. Start of nutritional therapy with Intestamin or control supplement within 24 hours after inclusion criteria are fulfilled

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Age <18 , for both sexes
2. Body weight <50 kg or >130 kg (estimated)
3. Pregnant and lactating women, women of child-bearing age. Pregnancy in women of child-bearing age should be ruled out with a pregnancy test.
4. Gastrointestinal obstructions, high output enterocutaneous fistulae
5. Severe diarrhoea unresponsive to codeine or loperamide
6. Biopsy proven cirrhosis and documented portal hypertension; episodes of past upper gastrointestinal bleeding attributed to portal hypertension; prior episodes of hepatic failure, encephalopathy or coma

7. Human immunodeficiency virus (HIV)-positive patients with an aquired immune deficiency syndrome (AIDS)-defining process, such as Pneumocystis carnii pneumonia, Kaposis sarcoma, progressive multifocal leukoncephalopathy (PML), Mycobacterium avium disease, Epstein-Barr virus (EBV) infection, or lymphoma, or a known CD4 count <200 cells/µl
8. Simultaneous participation in another clinical study

Date of first enrolment
01/01/2006

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Adult Intensive Care Unit
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Fresenius Kabi Deutschland GmbH (Germany)

ROR
https://ror.org/01v376g59

Funder(s)

Funder type
Industry

Funder Name
Fresenius Kabi GmbH (Germany)

Results and Publications

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	01/01/2008		Yes	No