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Parenteral Fish Oil in Sepsis

Submission date	Recruitment status	[_] Prospectively registered
09/11/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/11/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/01/2010	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
Intensive Care Unit
Hospital Padre Americo
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Effects of fish oil containing lipid emulsion on plasma phospholipid fatty acids, inflammatory markers, and clinical outcomes in septic patients: a randomised, controlled clinical trial

Acronym
FOS

Study objectives
Parenteral fish oil will reduce inflammation and improve clinical outcomes in septic patients in the intensive care unit (ICU).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comissão de Ética para a Saúde, Hospital Padre Américo, Penafiel, Portugal, approved on the 7th February 2007 (reg. no.: 1142; chair: Dr Braga da Cunha)

Study design
Randomised controlled parallel trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Systemic inflammatory response syndrome/sepsis

Interventions
Total parenteral nutrition including a lipid mixture providing a 50:50 mixture of coconut oil and soybean oil (Nutriflex Lipid Special) versus total parenteral nutrition (Nutriflex Special) including a lipid mixture providing a 50:40:10 mixture of coconut oil, soybean oil and fish oil (Lipoplus). Parenteral nutrition was administered continuously over 24 hours from soon after admission to the ICU until enteral feeding could be initiated, which was beyond day 6. Study samples were collected until day 6 and patient follow-up continued until they left hospital.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Parenteral fish oil

Primary outcome(s)
1. Plasma phospholipid fatty acid status at days 0, 1, 2 and 6
2. Plasma inflammatory cytokines at days 0, 1, 2 and 6
3. Inflammatory cytokine production by endotoxin stimulated whole blood at days 0, 1, 2 and 6
4. Length of ICU and hospital stay

Key secondary outcome(s))
1. Respiratory function at days 0, 1, 2 and 6
2. Mortality up to day 28

Completion date

31/12/2007

Eligibility

Key inclusion criteria
1. Systemic inflammatory response syndrome or sepsis
2. Predicted to need parenteral nutrition
3. Assigned to ICU
4. Over 18 years of age, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Able to be enterally fed
2. Under 18 years of age

Date of first enrolment
01/03/2007

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Portugal

Study participating centre
Intensive Care Unit
Penafiel
Portugal
4560-007

Sponsor information

Organisation
Hospital Padre Americo (Portugal)

ROR
https://ror.org/003zfh275

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (UK) - provided by UK honoraria

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	01/07/2010		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes