

Parenteral Fish Oil in Sepsis

Submission date 09/11/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 17/11/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/01/2010	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

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

Secondary outcome measures

1. Respiratory function at days 0, 1, 2 and 6
2. Mortality up to day 28

Overall study start date

01/03/2007

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

25

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)

Sponsor details

c/o Dr E Lafuente

Intensive Care Unit

Guilhufe

Penafiel

Portugal

4560-007

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/003zfh275>

Funder(s)

Funder type

Other

Funder Name

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2010		Yes	No