ISRCTN63673813 https://doi.org/10.1186/ISRCTN63673813

Effect of an omega-3 fatty acid enriched lipid emulsion on acute respiratory distress syndrome (ARDS)

Submission date 23/06/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/06/2008	**Overall study status** Completed	
Last Edited 14/04/2011	**Condition category** Respiratory	

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
BBM-PH-H-0229

Study information

Scientific Title

Study objectives
The lipid emulsions generally used in the parenteral nutrition of critically ill patients are rich in long-chain triglycerides (LCT), especially linoleic acid. These preparations guarantee an optimal energy supply and prevent deficiency in essential fatty acids. These fatty acids can alter pulmonary gas exchange due to their potentially proinflammatory properties. Several studies suggest that lipid emulsions effects on pulmonary gas exchange could be mediated by arachidonic acid derivates, especially eicosanoids.

Linoleic acid is the precursor, through the arachidonic acid pathway, of series 2 and 4 eicosanoids. These molecules are mediators of inflammation with intense biological activity. A variety of studies show that eicosanoids have different effects on the lungs, acting on immune response, vasomotor tone, and/or inflammatory response.

Polyunsaturated fatty acids of the n-3 series (omega-3), which are derived from alpha-linolenic acid, as well as their derivatives eicosapentaenoic acid and docosahexaenoic acid are also precursors of biologically active substances, e.g. the series 3 and 5 eicosanoids. These molecules use the same metabolic routes and compete for the same elongases and desaturases as linoleic and arachidonic, but ultimately they are mediators that have a much less active biological profile than linoleic acid derivatives. Due to the different composition in fatty acids of diversal lipid emulsions, its endovenous administration could have different physiologic and pharmacologic effects beside energetic properties in high risk patients.

In this study we will try to evaluate the effect and security of a lipid emulsion enriched with omega 3 fatty acids, in patients with acute respiratory distress syndrome (ARDS). Our hypothesis was that the use of an emulsion with less linoleic acid and enriched with omega-3 would reduce the pulmonary impact in patients with ARDS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Committee of Clinical Trials of the Vall d'Hebron General University Hospital of Barcelona on the 27th January 1999.

Study design
Prospective double blind randomised single-centre phase III study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute respiratory distress syndrome (ARDS)

Interventions
In the first 48 hours after the diagnosis of ARDS and before receiving artificial nutrition, patients were randomised into two different groups:
Group A received the study emulsion Lipoplus® 20% (B. Braun Medical; 50% MCT, 40% LCT, 10% omega-3)
Group B received the control emulsion Intralipid® 20% (Fresenius Kabi; 100% LCT)
The lipid emulsions were administered during 12 hours at a rate of 0.12 g/kg/h.

Measurements were made at baseline (immediately before the administration of lipid emulsions [t = 0]), at the end of administration (t = 12) and 24 hours after the beginning of lipid emulsion. Basic parameters of pulmonary mechanics, arterial and mixed venous gas analysis, haemodynamic parameters, and oxygen transport were measured at all stages. Measurement of different plasmatic eicosanoids (Thromboxane B2 [TXB2], 6-Keto-prostaglandin-F1 alfa and Leukotriene B4 [LTB4]) in mixed venous and arterial blood samples also took place during all the study periods.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Lipoplus®, Intralipid®

Primary outcome measure
1. Initial tolerance and security of an omega-3 fatty acid enriched lipid emulsion in patients with ARDS, evaluated during all the treatment period and up to the end of the ICU period
2. Effects on haemodynamics and respiratory function, measured at baseline, 6 hours, 12 hours (parenteral treatment ending), 24 hours (12 hours after parenteral ending)

Secondary outcome measures
Effects on eicosanoid synthesis, measured at baseline, 6 hours, 12 hours and 24 hours.

Overall study start date
10/08/2000

Completion date
13/03/2003

Eligibility

Key inclusion criteria
1. Patients aged 18 - 85 years, either sex
2. ARDS in the first 48 hours of admission
3. Intolerance of enteral nutrition

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
16

Key exclusion criteria
1. Aged younger than 18 or older than 85 years
2. Pregnancy
3. Liver failure
4. Human immunodeficiency virus (HIV) positivity
5. Leukopenia (less than 3500 mm^3)
6. Thrombocytopenia (less than 100,000 mm^3)
7. Severe renal insufficiency (creatinine greater than 6 mg/dl) or need for renal dialysis
8. Signs of heart failure
9. Transplantation
10. Multiple blood transfusions
11. Participation in other clinical trials simultaneously or in the last 60 days
12. Treatment with nitrous oxide or corticoids (prednisolone 2 mg/kg/d or equivalent)
13. Multiple organ failure
14. Severe dyslipidemia, or propofol treatment

Date of first enrolment
10/08/2000

Date of final enrolment
13/03/2003

Locations

Countries of recruitment
Spain

Study participating centre

Unitat de Suport Nutricional
Barcelona
Spain
08035

Sponsor information

Organisation
B. Braun Medical S.A. (Spain)

Sponsor details
Carretera de Terrassa, 121
Rubí (Barcelona)
Spain
08191

Sponsor type
Industry

Website
http://www.bbraun.es/

ROR
https://ror.org/04sdeyq07

Funder(s)

Funder type
Industry

Funder Name
B. Braun Medical S.A. (Spain)

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	08/04/2011		Yes	No