

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

<b>Submission date</b> 23/06/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/06/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/04/2011	<b>Condition category</b> Respiratory	<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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## 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 derivatives, 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<sup>3</sup>)
6. Thrombocytopenia (less than 100,000 mm<sup>3</sup>)
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?
<a href="#">Results article</a>	results	08/04/2011		Yes	No