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A double-blind, randomised study comparing the safety and tolerance of SMOFlipid 20% and Intralipid 20% in long-term treatment with parenteral nutrition

Submission date 11/07/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/08/2006	**Overall study status** Completed	
Last Edited 25/04/2014	**Condition category** Nutritional, Metabolic, Endocrine	

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
Protocol No.: 05-SMOF-006

Study information

Scientific Title

Study objectives
To demonstrate the comparability in safety and tolerance between SMOFlipid 20% and Intralipid 20%.

Please note that as of 9th October 2007, some changes were made to this record. The main changes were an update in ethics approval (previously no ethics information in the record), an update to the countries of recruitment (Germany dropped out and Poland joined) and an update to the anticipated start and end dates of the trial (these were moved forward).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee (EC) approval in all countries, except Australia as of 9th October 2007

Study design
Multi-national, multi-centre, randomised, active-controlled, double-blind, parallel study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Parenteral nutrition/malnutrition

Interventions
There were 48 patients per protocol from five European and two non-European countries. The interventions of this trial were the comparing of SMOFlipid 20% and Intralipid 20% on long-term treatment.

Please note that as of 9th October 2007, the anticipated start and end dates of this trial were delayed. The previous start and end dates of this trial were:

Original anticipated start date: 15/10/2006
Original anticipated end date: 31/12/2007

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
SMOFlipid 20% and Intralipid 20%

Primary outcome measure
1. Laboratory variables:
1.1. Clinical chemistry parameters: triglycerides, total cholesterol AP, Aspartate Aminotransferase (AST - also known as S-GOT), gamma Glutamyl Transferase (g-GT), Alanine Aminotransferase (ALT - also known as S-GPT), sodium, potassium, chloride, magnesium, calcium, phosphate, total bilirubin, S-creatinine, urea, glucose, albumin, total protein, C-Reactive Protein
1.2. Haematology parameters: leucocytes, platelets, erythrocytes, haemoglobin, haematocrit,
1.3. Coagulation parameters: International Normalised Ratio (INR)
2. Adverse events
3. Vital signs: blood pressure (mmHg), heart rate (beats/min), body temperature (°C)
4. Lipid metabolism

Rating of the safety and tolerance variables will be according to Common Terminology Criteria for Adverse Events.

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/10/2007

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Male and female subjects between 18 and 85 years of age
2. In- or out-patients unable to sustain an adequate oral/enteral food intake for at least four weeks and need of parenteral nutrition
3. Written informed consent from the subject

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
48 patients per protocol

Key exclusion criteria
1. Known hypersensitivity to fish, egg or soy protein or to any of the active substances or excipients
2. Known type IV hyperlipidemia, disturbances in lipid metabolism or hypertriglyceridemia. If the fasting S-triglyceride value at the time of inclusion is mopre than 3 mmol/l (>262.5 mg/dl) the subject must be withdrawn
3. Severe liver insufficiency
4. Severe blood coagulation disorders
5. Subjects with chronic stable renal insufficiency defined as S-creatinine value of more than 25 mg/l (200 µmol/l) or receiving dialysis/hemofiltration therapy
6. General contraindications to infusion therapy: acute pulmonary oedema, hyperhydration, decompensated cardiac insufficiency
7. Unstable conditions (e.g. severe post-traumatic conditions, uncompensated diabetes mellitus, acute myocardial infarction, stroke, embolism, metabolic acidosis, severe sepsis and hypotonic dehydration)
8. Unstable angina pectoris
9. Acute shock
10. Chemotherapy within four weeks before start of the trial
11. Chemotherapy during the trial
12. Subjects for whom the trial treatment (amounts, contents etc.) is not appropriate
13. Female patients must be surgically sterile, or postmenopausal for at least two years, or if of childbearing potential must have a negative serum pregnancy test and must agree to maintain adequate birth control practice during the study (e.g. hormonal contraceptives, contraceptive coil)
14. Participation in another clinical study with an investigational drug or an investigational medical device within one month prior to start of study or during the study
15. Prior inclusion in the present study
16. Any other feature that in the opinion of the investigator should preclude study participation

Date of first enrolment
15/10/2007

Date of final enrolment
31/12/2008

Locations

Countries of recruitment

Australia

Denmark

England

France

Israel

Netherlands

Poland

United Kingdom

Study participating centre
Consultant Gastroenterologist
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Sponsor information

Organisation
Fresenius Kabi Deutschland GmbH (Germany)

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Kabi Strategic Business Center
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Sponsor type
Industry

Website
http://www.fresenius-kabi.com

ROR
https://ror.org/01v376g59

Funder(s)

Funder type
Industry

Funder Name
Fresenius Kabi Deutschland GmbH (Germany)

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	01/04/2013		Yes	No