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

Recruitment status No longer recruiting	[X] Prospectively registered		
	☐ Protocol		
Overall study status Completed	Statistical analysis plan		
	[X] Results		
Condition category	[] Individual participant data		
	No longer recruiting Overall study status Completed		

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

Protocol serial number

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

Study type(s)

Treatment

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(s)

- 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.

Key secondary outcome(s))

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

85 years

Sex

All

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
United Kingdom
England

Australia

Denmark

France

Israel

Netherlands

Poland

Study participating centre Consultant Gastroenterologist Manchester United Kingdom M6 8HD

Sponsor information

Organisation

Fresenius Kabi Deutschland GmbH (Germany)

ROR

https://ror.org/01v376g59

Funder(s)

Funder type

Industry

Funder Name

Fresenius Kabi Deutschland GmbH (Germany)

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	01/04/2013		Yes	No