



Clinical trial results: Fish OIL optimal dose Determination Study Summary

EudraCT number	2010-021018-49
Trial protocol	DE
Global end of trial date	15 December 2017

Results information

Result version number	v1 (current)
This version publication date	06 June 2024
First version publication date	06 June 2024

Trial information

Trial identification

Sponsor protocol code	FOILED
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01146821
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GWT-TUD GmbH
Sponsor organisation address	Freiberger Str. 33, Dresden, Germany, 01067
Public contact	Medical Consulting, GWT-TUD GmbH, +49 35125933100, medical.consulting@g-wt.de
Scientific contact	Medical Consulting, GWT-TUD GmbH, +49 35125933100, medical.consulting@g-wt.de

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	28 June 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 December 2017
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To determine the safety and efficacy of IV fish oil doses of 0.20 g/kg and 0.50 g/kg, compared to a control group, in critically ill patients with severe sepsis by examining organ function, blood safety and biochemical parameters, markers of systemic inflammation and innate immunological parameters.

Protection of trial subjects:

The conduct of this study was in compliance with the Good Clinical Practice Guidelines and under the guiding principles detailed in the Declaration of Helsinki. The study was also carried out in keeping with applicable local law(s) and regulation(s).

Upon enrollment (prior to initiation of the study interventions) and daily thereafter for the study duration in the ICU, measurement daily parameters. In addition, monitoring routine measurements of liver function tests (AST, ALT, GGT, and bilirubin) and blood urea nitrogen when clinically available and will follow study patients in ICU to evaluate tolerance of enteral nutrition and total nutritional adequacy (including propofol use).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 March 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 7
Worldwide total number of subjects	7
EEA total number of subjects	7

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0

Adults (18-64 years)	0
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The present trial enrolled patients from May 2012 and was preliminary stopped due to lack of recruitment after completion of the control group (n=7) in March 2017. The present trial was initially planned as a two-center open-label, phase II dose ranging clinical trial with prospective controls.

Pre-assignment

Screening details:

Consecutive patients admitted to the ICU with sepsis were screened for possible enrollment in the trial. The first patient was enrolled in March 2015.

Period 1

Period 1 title	Group 1 (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Group 1
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Arm description:

A consecutive cohort of 7 patients who met the eligibility criteria serving as controls. This group received no fish oils but routine clinical and biochemical measurements were performed in this group similar to the subsequent groups.

Arm type	standard care
Investigational medicinal product name	Highly refined fish oil
Investigational medicinal product code	
Other name	Omegaven®
Pharmaceutical forms	Emulsion for infusion
Routes of administration	Infusion

Dosage and administration details:

No study intervention. This group received no fish oils but routine clinical and biochemical measurements were performed in this group similar to the subsequent groups.

Number of subjects in period 1	Group 1
Started	7
Completed	7

Baseline characteristics

End points

End points reporting groups

Reporting group title	Group 1
Reporting group description: A consecutive cohort of 7 patients who met the eligibility criteria serving as controls. This group received no fish oils but routine clinical and biochemical measurements were performed in this group similar to the subsequent groups.	

Primary: Change in Sequential Organ Failure Assessment score (organ function)

End point title	Change in Sequential Organ Failure Assessment score (organ function) ^[1]
End point description:	
End point type	Primary
End point timeframe: 14 days	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The present trial enrolled patients from May 2012 and was preliminary stopped due to lack of recruitment after completion of the control group (n=7) in March 2017. Patients with severe sepsis and septic shock (initial SOFA 13±1). Caused mainly by peritonitis (85.7%). Hospital mortality was 28.6% and 28-day mortality 14.3%. ICU length of stay was 15 (6-36) days and hospital length of stay was 34 (14-69) days.

End point values	Group 1			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: 1	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

12 month

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	18.1
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Reporting groups

Reporting group title	Overall
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Reporting group description: -

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: There were no non-serious adverse events reported.

Serious adverse events	Overall		
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	2		
Injury, poisoning and procedural complications			
Post procedural complication			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Multiple organ failure			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Immune system disorders			
Anaphylactic reaction			

subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal compartment syndrome			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bacterial infection			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
New septic shock			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Overall		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 7 (0.00%)		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 May 2015	Protocol V2.1

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The trial was stopped after completion of group 1 due to lack of recruitment.

Notes: