Clinical trial results:
RANDOMIZED CONTROLLED TRIAL OF THE EFFECTS OF PARENTERAL FISH OIL EMULSION UPON SURVIVAL OUTCOME OF CRITICALLY ILL SEPTIC PATIENTS IN THE INTENSIVE CARE UNIT

Summary

EudraCT number	2009-016880-13
Trial protocol	GB
Global end of trial date	10 April 2014

Results information

Result version number	v1 (current)
This version publication date	26 June 2020
First version publication date	26 June 2020

Trial information

Trial identification

Sponsor protocol code	ITU version1 19/10/2009

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	University Hospitals of Leicester
Sponsor organisation address	Research and Innovation. Leicester General Hospital, Gwendolen Road, Leicester, United Kingdom, LE5 4PW
Public contact	Carolyn Maloney Head of Operations R&D Office. Leicester General Hospital LE5 4PW, University Hospitals of Leicester NHS Trust , + 44 116 2588110, ashley.dennison@uhl-tr.nhs.uk
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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	01 September 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 April 2014
Global end of trial reached?	Yes
Global end of trial date	10 April 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The effect of Omega 3 fatty acids on reduction of APACHE II score as a surrogate marker of mortality.

Protection of trial subjects:

The infusion of omegaven can cause a prolonged bleeding time and an inhibited platelet aggregation. Therefore shoudl be administered with caustion to patients requiring anti platelet therapy even with regard to a possible reduction of anticoagulants. There are no otehr known interactions.
Coagulations screens were performed on all subjects prior to recruitment and undertaken daily (as part of routien care) during the progress of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 May 2011
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	United Kingdom: 74
Worldwide total number of subjects	74
EEA total number of subjects	74

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)	35

From 65 to 84 years	34
85 years and over	5

Subject disposition

Recruitment

Recruitment details:

Recruitment 10.07.11 to 03.04.14. Single UK Centre

Participants will be identified by the direct care team on the intensive care unit, who will refer the patients to the researchers for consideration of enrolling in the study.

Pre-assignment

Screening details:

All critically ill septic patients admitted to the intensive care unit at Leicester General and Glenfield Hospital and the high dependency renal unit. Sepsis is defined as a systemic inflammatory response syndrome(SIRS) (Annexe 3) and the presence of a known of suspected infection.

Period 1

Period 1 title	Recruitment Overall Period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm 1

Arm description:

Omegaven Fish Oil Infusion

Arm type	Experimental
Investigational medicinal product name	Omegaven emulsion for infusion
Investigational medicinal product code	PR4
Other name	
Pharmaceutical forms	Emulsion for infusion
Routes of administration	Intravenous use

Dosage and administration details:

0.5mls omegaven per kilogram of body weight/hour corresponding to 0.05gms fish oil per kilogram of body weight per hour.
Total dose 0.05gram/0.5ml intravenous

Arm title	ARM 2

Arm description:

Standard Care

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Arm 1	ARM 2
Started	35	39
Completed	35	39

Baseline characteristics

End points

End points reporting groups	
Reporting group title	Arm 1
Reporting group description: Omegaven Fish Oil Infusion	
Reporting group title	ARM 2
Reporting group description: Standard Care	

Primary: Effect of Omega 3 fatty acids on the number of new organ dysfunction(not present at baseline/admission) as a predictor for teh outcome in sepsis	
End point title	Effect of Omega 3 fatty acids on the number of new organ dysfunction(not present at baseline/admission) as a predictor for teh outcome in sepsis
End point description:	
End point type	Primary
End point timeframe: pts observed over a maximum of 2 weeks	

End point values	Arm 1	ARM 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: numbers				
arithmetic mean (standard deviation)	30 (± 30)	30 (± 30)		

Statistical analyses

Statistical analysis title	stata software
Comparison groups	Arm 1 v ARM 2
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Regression, Linear
Parameter estimate	linear regression
Point estimate	0.05
Confidence interval	
level	95 %
sides	1-sided
lower limit	0.04

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Timepoint for reporting is until discharge from ITU/HDU or for a maximum period of 14 days

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups

Reporting group title	ARM1
Reporting group description: -	
Reporting group title	ARM2

Reporting group description:

Standard Care

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: No non-serious adverse events were recorded for this study

Serious adverse events	ARM1	ARM2	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 35 (11.43%)	6 / 39 (15.38%)	
number of deaths (all causes)	3	6	
number of deaths resulting from adverse events	3	6	
General disorders and administration site conditions			
Multi organ failure			
subjects affected / exposed	4 / 35 (11.43%)	6 / 39 (15.38%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 2	0 / 6	
Skin and subcutaneous tissue disorders			
Rash and Bruising	Additional description: Bruising and rash on arms legs and chest. Clotting was checked and normal.		
subjects affected / exposed	1 / 35 (2.86%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute Renal Failure			
subjects affected / exposed	1 / 35 (2.86%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	

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

Non-serious adverse events	ARM1	ARM2	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 35 (0.00%)	0 / 39 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported