ISRCTN11451475 https://doi.org/10.1186/ISRCTN11451475

Preventing new infections while patients are sick in hospital with omega-3 fatty acids

Submission date
05/12/2024

Recruitment status
Recruiting

Registration date
11/03/2025

Overall study status
Ongoing

Last Edited
04/06/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients admitted to the critical care unit often end up having new infections while they are in hospital, which can be very serious. Omega-3 fatty acids, which are fish oil extracts, may be helpful in reducing the number of people that have new infections and possibly, reduce the length of hospital stay. However, we need to find the correct dose that can be given to these patients. This study will help us establish a dose that can be given to similar patients in future and build a case for future studies.

Who can participate?
Patients aged 18 years and over admitted to the Intensive Care Unit

What does the study involve?
Participants will be randomly allocated to receive either omega-3 fatty acids for 10 days, or standard care (no extra treatments).

What are the possible benefits and risks of participating?
We are not expecting any serious side effects to occur during this study. Omegaven has fish oil, is a licensed drug in the EU, and has been used safely in other groups, including healthy people, people with liver problems and children. Some patients have experienced vomiting or had a rash. We cannot promise that there will be benefits, but we are trying to understand if giving patients Omegaven prevents them from getting serious infections while in hospital.

Where is the study run from?
The Royal London Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2022 to December 2026

Who is funding the study?
Fresenius Kabi (Germany)

Who is the main contact?
Prof. Zudin Puthucheary, z.puthucheary@qmul.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Zudin Puthucheary

Contact details
Adult Critical Care Unit
Royal London Hospital
Whitechapel
London
United Kingdom
E1 1BB
+44 (0)20 35940351
z.puthucheary@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1008285

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
158743 Sponsor EDGE reference, CPMS 59166

Study information

Scientific Title
Hospital-acquired Infection Prevention with Parenteral Omegaven (HIPPO)

Acronym
HIPPO

Study objectives
Hospital-acquired infections (HAI) are new infections that are typically not present at admission and manifest 48 hours after hospital admission. Several studies have highlighted the potentially beneficial effects of using omega-3 FAs (fish oil) in critically ill patients to lower inflammation and suggest a significant reduction in nosocomial (hospital-acquired) infections may occur in

patients receiving total parenteral (outside of the digestive tract) nutrition prepared with a lipid emulsion. However, the acceptable dose that needs to be administered and is tolerated by patients needs to be determined. This will be clarified in a dose-escalation randomised controlled trial. The inclusion of a control (standard care) group will provide information on the expected baseline levels of the outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/02/2025, London - Fulham Research Ethics Committee (2 Redman Place, Stratford, London , E20 1JQ, United Kingdom; -; fulham.rec@hra.nhs.uk), ref: 24/LO/0914

Study design
Single-centre randomized controlled dose-escalation trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment, Safety, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Prevention of hospital-acquired infection in adult, critically ill patients

Interventions
Following consent, the intervention will start within 48 hours of critical care admission and continue for 10 days or until hospital discharge, whichever is sooner. Randomisation will be performed using an electronic randomisation system embedded within the online trial database.

Intervention arm:
Participants will be randomised sequentially in three dosing phases (0.2, 0.4, 0.6 g/kg/d Omegaven) according to the Bayesian Optimal Interval dose-escalation plan. Omegaven will be provided based on bodyweight in kg, except in cases of morbidly obese patients (actual bodyweight >200% of the ideal bodyweight).

Patients will receive intravenous Omegaven, administered daily (at any time within a 24-hour period) until day 10 or hospital discharge, whichever is sooner. Omegaven will be administered centrally if available and if this is not possible it will be given peripherally.

Standard care arm:
Patients in the standard care group will be managed by clinical staff according to local policy and guidelines until hospital discharge. No additional interventions will occur.

Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacodynamic, Dose response

Phase
Phase II

Drug/device/biological/vaccine name(s)
Omegaven

Primary outcome measure
The maximum tolerable dose (MTD) of Omegaven, calculated after the completion of the dose escalation based on the dose-limiting toxicity, which is in turn based on a review of adverse events attributable to the IMP

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
06/01/2022

Completion date
15/12/2026

Eligibility

Key inclusion criteria
1. Patients aged 18 years and over
2. Patients requiring intubation and ventilation OR requiring two or more other organ systems support (Sequential Organ Failure Assessment [SOFA] score ≥2 in >2 domains) without requiring intubation and ventilation
3. Patients predicted to remain in the critical care unit for at least 72 hours as determined by the Intensive Care Consultant with clinical responsibility for patient care

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
110 Years

Sex
Both

Target number of participants
36

Key exclusion criteria
1. Patients requiring total parenteral nutrition at time of enrolment
2. Palliative care admission for end-of-life care or withdrawal of active therapyas determined by the Intensive Care Consultant with clinical responsibility for patient care
3. Neutropaenia(<1 x 10^9/l) on admission to the Adult Critical Care Unit
4. Lymphopenia (<0.25 x 10^9/l)on admission to the Adult Critical Care Unit
5. Primary immune deficiency
6. Bone marrow transplant recipient
7. All immunosuppressive drug therapy (with the exception of corticosteroid use for acute illnesses in the preceding 5 days)
8. Recorded or reported allergy to fish, or egg protein or to any of the active ingredients or excipients
9. Known inborn errors of lipid metabolism
10. Recorded or reported severe hyperlipidaemia or severe disorders of lipid metabolism (electronic health record documentation ± clinical concern and if available with serum triglycerides >400 mg/dl on admission to the Adult Critical Care Unit)
11. Enrolment in any other study with an IMP or a study that may have a similar primary outcome
12. Therapeutic anti-coagulation therapy
13. Pregnancy

Date of first enrolment
01/08/2025

Date of final enrolment
01/05/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Sponsor information

Organisation
Queen Mary University of London

Sponsor details
Research Services, Dept. W
c/o Mile End Post Room
Queen Mary University of London
327 Mile End Road
London
England
United Kingdom
E1 4NS
+44 (0)20 7882 7275
research.governance@qmul.ac.uk

Sponsor type
University/education

Website
http://www.qmul.ac.uk/

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Industry

Funder Name
Fresenius Kabi

Alternative Name(s)
Fresenius Kabi AG, Fresenius Kabi Deutschland GmbH

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Results and Publications

Publication and dissemination plan
Data arising from this research will be made available to the scientific community in a timely and responsible manner. A detailed scientific report will be submitted to a widely accessible scientific journal on behalf of the HIPPO Trial Group. The trial steering committee will agree on the membership of a writing committee, which will take primary responsibility for the final data analysis and writing of the scientific report. All members of the writing committee will comply with internationally agreed requirements for authorship and will approve the final manuscript prior to submission.

Intention to publish date
15/06/2027

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date