Pilot study to investigate dietary supplementation of elderly COPD patients with an oral nutritional supplement enriched with n-3 polyunsaturated fatty acids and its effect on respiratory function, appetite and weight

Submission date	Recruitment status	Prospectively registered
30/09/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2005	Completed	Results
Last Edited	Condition category	Individual participant data
10/05/2018	Respiratory	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Gary Frost

Contact details

Nutrition & Dietetics Department 2nd Floor, C Block Hammersmith Hospital Du Cane Road London United Kingdom W12 0HS +44 (0)20 8383 3048(bleep 9027) g.frost@imperial.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0016148139

Study information

Scientific Title

Pilot study to investigate dietary supplementation of elderly COPD patients with an oral nutritional supplement enriched with n-3 polyunsaturated fatty acids and its effect on respiratory function, appetite and weight

Study objectives

Does the addition of fish oil to a complete nutritional supplement make supplementation more effective? i.e. do patients gain more weight, improve their lung function and exercise tolerance and report improved appetite when compared to patients using supplements without fish oils?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Chronic obstructive pulmonary disease (COPD)

Interventions

Randomised controlled trial

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Improved lung function
- 2. Decreased sytokine responses.

Fish oils have been used with promising results in other wasting conditions such as HIV, cancer and sepsis. There are no published trials investigating the possible benefits of fish oil supplementation in COPD patients and this proposal aims to do this.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/07/2002

Completion date

01/07/2003

Eligibility

Key inclusion criteria

Out patients from COPD clinic at the Hammersmith Hospitals NHS Trust

Participant type(s)

Patient

Age group

Senior

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/07/2002

Date of final enrolment

01/07/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Nutrition & Dietetics Department
London
United Kingdom
W12 0HS

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

Hammersmith Hospital NHS Trust (UK)

Funder Name

Hammersmith Hospital Trustees Research Committee (HHTRC) (UK)

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration