ISRCTN80844630 https://doi.org/10.1186/ISRCTN80844630

Omega 3 fatty acid for prevention of sickle cell crisis

Submission date
15/12/2011

Recruitment status
No longer recruiting

Registration date
23/01/2012

Overall study status
Completed

Last Edited
16/04/2019

Condition category
Haematological Disorders

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sickle cell anaemia is an inherited blood disease that affects millions of people worldwide. It is most common in Sub-Sahara Africa and among people whose ancestors come from this region. The disease causes blockage of blood flow and serious damage to the kidneys, lungs, brain and other vital organs of the body. Sickle cell patients at a high risk of organ damage are treated with regular blood transfusions and hydroxyurea. These treatments pose new risks for patients. Moreover, they are not readily available in Sub-Sahara Africa. Hence, there is a need for effective, affordable and safe treatment. The aim of the study is to investigate if omega 3 fatty acids, nutrients obtained from oil fish, prevent blockage of blood flow.

Who can participate?
140 male and female patients between 2 and 50 years old with sickle cell anaemia were recruited from the Sickle Cell Referral Clinic, Khartoum Teaching Hospital, Khartoum (Sudan).

What does the study involve?
The patients were given capsules (pills) with or without omega 3 fatty acids.

What are the possible benefits and risks of participating?
If omega 3 fatty acids are shown to prevent blockage of blood flow, it will be beneficial to the participants and others who have the disease. Omega 3 fatty acids are nutrients widely present in fish and other marine food and do not present any risk.

Where is the study run from?
All the patients were recruited from the Sickle Cell Referral Clinic, Ibn-Aoaf Paediatric Hospital (the lead centre) and Khartoum Teaching Hospital, Khartoum, Sudan.

When is the study starting and how long is it expected to run for?
The study started in June 2008 and completed in May 2010.

Who is funding the study?
1. Marie Curie Transfer of Knowledge (European Union)
2. University of Khartoum (Sudan)

3. Efamol Limited (UK)
4. The Kitchener School of Medicine Trust Fund (UK)

Who is the main contact?
Professor Kebreab Ghebremeskel
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Study website
http://www.londonmet.ac.uk/faculties/faculty-of-life-sciences-and-computing/research/lipidomics-and-nutrition-research-centre/research-projects/current/sickle-cell-disease---alternative-dietary-lipid-therapy/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Omega 3 Fatty Acids for prevention of vaso-occlusive and haemolytic crises in patients with homozygous Sickle Cell Disease (FASCD): a randomised, double-blind, placebo-controlled trial

Acronym
FASCD

Study objectives
1. Supplementation with the long-chain polyunsaturated omega-3 fatty acids, docosahexaenoic (DHA) and eicospentaenoic (EPA), will prevent vaso-occlusive and clinical vaso-occluive episodes in patients with homozygous sickle cell disease (HbSS)
2. DHA and EPA supplement will reduce haemolytic crisis, blood transfusion rate and number of school days lost due to illness related to the disease and heamoglobin concentration

Protocol can be found at: http://www.londonmet.ac.uk/faculties/faculty-of-life-sciences-and-computing/research/lipidomics-and-nutrition-research-centre/research-projects/current/sickle-cell-disease---alternative-dietary-lipid-therapy/

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of the Faculty of Medicine, University of Khartoum, Sudan, 19/04/2009
2. Research Ethics Committee of Southampton & South West Hampshire, UK, 18/05/2005, ref: 05/Q1702/48

Study design
Randomised double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Sickle cell anaemia (HbSS)

Interventions
The subjects, after stratification by age and gender, will be randomly assigned to receive coded and indistinguishable omega 3 (n=70) or placebo (n=70) capsules.

Subsequent to randomisation, the patients will be given, daily for one year, one (2-4 year old), two (5-10), three (11-16) or four (≥ 17) omega 3 containing 277.8 mg DHA and 39.0 mg EPA or high oleic acid (41%) oil blend placebo capsules. The antioxidant vitamin E, 1.5mg/capsule, was added to the omega 3 and placebo to prevent peroxidation.

Enrolment identification number, gender, residence, ethnicity, weight, height, history of blood transfusion and stroke, number of sickle cell-related hospital admission during the previous years and sickle cell complication data will be collected using a validated structured questionnaire at baseline. Monthly self-assessment health diary will be given to each patient to daily record, pain frequency and intensity, pain medication taken and hospitalisation. Name and telephone number of the medical doctor in charge will be given to the patients and their guardians in case they require advice or care outside normal working hours.

During each monthly follow-up, the self-recorded health diaries will be reviewed, patients examined thoroughly and the data obtained entered into the database by the same physician. Whole blood, about 10 ml, will be obtained from the patients at recruitment and after one year of intervention for haematological and biochemical analyses.

Intervention Type
Supplement

Primary outcome measure
1. Annualised rates of clinical vaso-occlusive crisis is defined as painful events that lead to hospitalisation.
1.1. Vaso-occlusive crisis is defined as a painful event characterised by musculoskeletal and/or visceral pain which is usually associated with mild pyrexia and the passage of dark or red urine.

Secondary outcome measures
1. Haemolytic crisis
2. Rate of blood transfusion
3. School attendance
4. Hb level and mean cell volume (MCV)

Overall study start date
12/06/2008

Completion date
30/05/2010

Eligibility

Key inclusion criteria
1. HbSS phenotype
2. Male and female participants
3. Steady state
4. Aged 2 to 50 years old

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
140

Key exclusion criteria
1. Other phenotypes
2. Patients in crisis
3. Patients on hydroxyurea treatment
4. Presence of other chronic diseases
5. Blood transfusion in the previous four months
6. Pregnancy
7. Previous history of overt stroke

Date of first enrolment
12/06/2008

Date of final enrolment
30/05/2010

Locations

Countries of recruitment
England

Sudan

United Kingdom

Study participating centre
Lipidomics and Nutrition Research Centre,
Faculty of Life Sciences and Computing,
London Metropolitan University
London
United Kingdom
N7 8DB

Study participating centre
Faculty of Medicine,
University of Khartum,
Khartum
Sudan
-

Study participating centre
Sickle Cell Disease Clinic Abnaof Paediatric Hospital,
Khartum

Sudan
-

Sponsor information

Organisation
Mother and Child Foundation (UK)

Sponsor details
36 Regents Park Road
London
United Kingdom
NW1 7SX

Sponsor type
Charity

Website
http://www.mother-and-child.org/

ROR
https://ror.org/030ybgp98

Funder(s)

Funder type
Research organisation

Funder Name
Marie Curie Transfer of Knowledge (EU) (ref: MTKD-CT-2005-029914)

Funder Name
University of Khartoum (Sudan)

Funder Name
Efamol Limited (UK)

Funder Name

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/01/2013		Yes	No
Results article	results	01/10/2013		Yes	No
Results article	results	01/12/2013		Yes	No
Results article	results	01/06/2015		Yes	No
Results article	results	01/10/2018		Yes	No