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Fish Oils in Lupus

Submission date	Recruitment status	[ ] Prospectively registered
22/07/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/07/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/12/2012	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2004-004404-21

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
073400

Study information

Scientific Title
Omega-3-polyunsaturated fatty acids and atherosclerosis in systemic lupus erythematosus: cellular mechanisms and functional consequences

Study objectives
AIMS:
1. To examine platelet free radical (nitric oxide and superoxide) generation in Systemic Lupus Erythematosus (SLE)
2. To examine endothelial function and vascular reactivity in systemic lupus erythematosus at global, local and microvascular levels
3. To examine the effect of omega-3 polyunsaturated fatty acids in relation to markers of platelet activation, vascular reactivity and disease activity in systemic lupus erythematosus

Ethics approval required
Old ethics approval format

Ethics approval(s)
QUB Research Ethics Committee (reconstituted to ORECNI 2004) gave approval on the 28th May 2003 (MHRA letter of approval on 10th December 2004). Reference numbers:
1. Ethics: 158/03
2. Trust: 04/SW/114
3. Eudract No.: 2004-004404-21
4. CTA No.: 21993-0002-001-0001

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Systemic Lupus Erythematosus (SLE)

Interventions
SLE subjects will be randomised to either fish oil capsules or placebo for a 24 week period. The patients will have measures of endothelial function and vascular reactivity, free radical activity and markers of disease activity taken at baseline, 12 weeks and at 24 weeks.

Joint sponsor details:
Greenpark Healthcare Trust
Research Department
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Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Fish oil capsules

Primary outcome measure
Improved nitric oxide bioactivity and reduced superoxide bioactivity.

Secondary outcome measures
Improved vascular reactivity and endothelial function, clinical response as measured by Revised activity index of Systemic Lupus Activity Measure (SLAM-R), Systemic Lupus International Collaborating Clinics (SLICC) and British Isles Lupus Assessment Group (BILAG).

Overall study start date
01/01/2005

Completion date
01/08/2006

Eligibility

Key inclusion criteria
Patients (adult, either sex) fulfilling American College of Rheumatology (ACR) classification criteria for SLE.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Diabetes mellitus (fasting blood glucose more than 7.8 mmol/l)
2. Hypertension of systolic more than 160 mmHg or diastolic more than 90 mmHg (as determined by the mean of three readings taken on the first visit)
3. Carcinoma (other than superficial skin carcinoma)
4. Significant pulmonary, hepatic or renal disease
5. Typical angina or myocardial infarction
6. Active infectious diseases
7. Use of antihypertensive, oral hypoglycaemic or lipid lowering agent (in the last three months)
8. Cyclophosphamide therapy (due to potential to interfere with acetylcholinesterase)
9. Glucocorticoids equivalent to greater than 10 mg prednisolone
10. All pregnant or lactating women will be excluded.

Date of first enrolment
01/01/2005

Date of final enrolment
01/08/2006

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Queen's University of Belfast
Belfast
United Kingdom
BT7 1BL

Sponsor information

Organisation
Queen's University of Belfast (UK)

Sponsor details
Lanyon North
Regional Research Services
University Road
Belfast

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BT7 1NN
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Sponsor type
University/education

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

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 073400)

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	01/06/2008		Yes	No