

Fish Oils in Lupus

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

2004-004404-21

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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

Musgrave Park Hospital

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Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Fish oil capsules

Primary outcome(s)

Improved nitric oxide bioactivity and reduced superoxide bioactivity.

Key secondary outcome(s)

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).

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

Northern Ireland

Study participating centre

Queen's University of Belfast

Belfast

United Kingdom

BT7 1BL

Sponsor information

Organisation

Queen's University of Belfast (UK)

ROR

<https://ror.org/00hswnk62>

Funder(s)

Funder type

Charity

Funder Name

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

Results and Publications

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