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The role of omega-3 fatty acids in the management of rotator cuff tendinopathy.

Submission date
03/06/2015

Recruitment status
No longer recruiting

Registration date
05/06/2015

Overall study status
Completed

Last Edited
27/11/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
The rotator cuff is a group of muscles and their tendons in the shoulder. Rotator cuff tendinopathy is defined as pain and dysfunction of one or more of those tendons (called supraspinatus, infraspinatus, subscapularis and teres minor). Exercise is the most common and relatively effective treatment . However, although the results are comparable to surgery, not everyone responds positively or completely. There is a definitive need to identify new methods to support current practice and in order to improve outcomes. Nutritional supplements are marketed to people suffering musculoskeletal symptoms, such as joint degeneration and tendinopathy. Omega-3 poly unsaturated fatty acids (PUFAs) have been recommended for people suffering from tendinopathy, with one potential benefit being a reduction in inflammation which may be present in tendinopathy. The aim of this study is to compare exercise and PUFAs to exercise and placebo supplements.

Who can participate?
Adults diagnosed with Rotator cuff tendinopathy.

What does the study involve?
Participants are randomly allocated to one of two groups: exercise and PUFAs group or exercise and dummy supplements group.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
3 sites in London (UK): Guy's and St Thomas' NHS Foundation Trust, St George's Foundation NHS Trust and Health at the Stowe, Westminster PCT / Central London Community Healthcare NHS Trust

When is the study starting and how long is it expected to run for?
June 2008 to December 2012

Who is funding the study?
Seven Seas (UK)

Who is the main contact?
Ms Fiona Sandford
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Contact information

Type(s)
Scientific

Contact name
Mrs Fiona Sandford

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised single blinded placebo controlled study investigating the role of poly unsaturated fatty acids in addition to exercise in the management of rotator cuff tendinopathy

Study objectives
Poly unsaturated fatty acid supplementation will result in significant improvement in disability (as measured by the Oxford Shoulder Score) or the experience of pain when compared to placebo when assessed at 2 months, 3 months, 6 months and one year.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Main REC: NRES Committee London-Bromley, ref: 08/H0805/21

Study design
Multi-centre interventional randomised placebo 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
Rotator cuff tendinopathy

Interventions
The active supplements used in this trial were MaxEPA supplements (Seven Seas Ltd, Hull, UK). They are gelatine coated capsules, oval in shape and brown tan in colour, containing 170mg EPA, 115mg DHA, 100 units/g vitamin E and 10 units/g vitamin D. The placebo supplement looked identical but contained mixed inert oil in place of the EPA and DHA. Participants in both groups were asked to take 9 soft shell capsules per day for a total of 2 months. Both groups also attended an exercise group once a week for a total of 8 weeks.

Intervention Type
Supplement

Primary outcome measure
The Oxford shoulder score questionnaire was used at baseline, 2 months, 3 months, 6 months and 12 months.

Secondary outcome measures
1. Numerical rating score for pain
2. Shoulder Pain and Disability Index (SPADI)
3. Patient specific functional score (PSFS): a questionnaire used to quantify activity limitation and measure functional outcome in areas chosen by the patient specifically
4. EuroQol D5-3L (EQ-D5-3L) health questionnaire: a measure of health related quality of life
5. Short Form (SF)-36
6. Global perception of change
7. Range of glenohumeral range of motion (flexion/abduction/internal and external rotation, hand behind back)
8. Shoulder strength (shoulder flexion/abduction/internal and external rotation and biceps strength).

All taken at baseline, 2 months, 3 months, 6 months and 12 months.

Overall study start date
01/06/2008

Completion date
12/12/2012

Eligibility

Key inclusion criteria
The study aimed to recruit men and women aged 18 to 80 years, who were referred for physiotherapy to one of four physiotherapy departments with a diagnosis of unilateral RC tendinopathy.
1. Unilateral shoulder pain of more than 3 months duration (anterior &/or antero-lateral
2. Pain produced or increased during flexion and/or abduction of the symptomatic shoulder
3. Failure of conservative management (manual therapy, exercises, injections, electrotherapy NSAIDS)
4. At least 4 of the following:
4.1 Positive Neer's impingement sign
4.2 Positive Hawkins & Kennedy test
4.3 Pain & weakness reproduced on full & empty can test
4.4 Pain & weakness on resisted shoulder external rotation
4.5 Pain on palpation over greater tuberosity of humerus

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
72

Total final enrolment
73

Key exclusion criteria
1. Outside age range of 18-80 years
2. Known allergy to fish or fish products
3. Unwilling to take fish oils
4. Currently taking high dose fish oils (over 1g daily).
5. Diabetes
6. Pregnancy or breast feeding

7. Reproduction of shoulder symptoms during active cervical spine movements
8. Post traumatic onset of symptoms
9. Radiographic or clinical evidence of shoulder instability (sulcus, anterior/posterior draw, relocation test, apprehension test)

Date of first enrolment
18/12/2008

Date of final enrolment
18/01/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's and St Thomas' Foundation NHS Trust
London
United Kingdom
SE1 7EH

Study participating centre
St George's Foundation NHS Trust
London
United Kingdom
SW17 0QT

Study participating centre
Health at the Stowe, Westminster PCT / Central London Community Healthcare NHS Trust
London
United Kingdom
SW1E 6QP

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

Sponsor details
Westminster Bridge Road
London
England
United Kingdom
SE1 7EH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Industry

Funder Name
Seven Seas provided the supplements and placebos

Funder Name
St Georges's charitable foundation- medical research

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/10/2018	27/11/2019	Yes	No