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N3 fatty acids as adjuvant therapy in rheumatoid arthritis (N3-fettsäuren als adjuvante therapie bei rheumatoider arthritis)

Submission date 01/12/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 03/01/2008	**Overall study status** Completed	
Last Edited 03/01/2008	**Condition category** 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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10-184 ex 99/00

Study information

Scientific Title

Study objectives
Omega-3 fatty acids infusions may show earlier and superior antiinflammatory effects in patients with rheumatoid arthritis than oral administered ones (as shown in earlier trials), and we presumed the beneficial effects may be maintained by following oral omega-3 fatty acid administration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This trial was approved by the ethics committee of the Medical University of Graz on 10th July 2000.

Study design
Randomized, double-blinded, placebo-controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions
Intervention group: Infusions of omega-3 fatty acids once daily for 14 days (Infusion speed: 0.5 ml /kg body weight and hour), followed by oral administration of omega-3 fatty acids up to 6 months.

Control group: Placebo infusions once daily for 14 days (Infusion speed: 0.5 ml/kg body weight and hour), followed by oral administration of placebo up to 6 months.

Verum:
Infusions: Fish oil emulsion (Omegaven® Fresenius). 100 ml Omegaven® contained 10 g fish oil with 2.03 g EicosaPentaenoic Acid (EPA) and 2.26 g DocosaHexaenoic Acid (DHA) (and 0.02 mg a-tocopherol as antioxidat)

Capsules: Fish oil. One capsule contained 1 g fish oil with 0.20 g EPA and 0.23 g DHA (and 0.02 mg a-tocopherol as antioxidant)

Placebo:
Infusions: NaCl 0.9% (physiological sodium chloride solution)
Capsules: Paraffin wax

Randomisation was done by a hospital pharmacist who prepared the bottles and other infusion material, so that neither the patients nor the staff could identify them as verum or placebo. Additionally, the study conducting staff was not allowed to enter the inpatient area while the patients received their infusions.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Omega-3 fatty acids

Primary outcome measure
The following were assessed at baseline, during infusion phase (after week 1 and after week 2) and during capsule phase (after two weeks [end of month 1] and then monthly until the end of month 6):
1. Swollen joints
2. Tender joints
3. Erythrocyte Sedimentation Rate (ESR)
4. C-Reactive Protein (CRP)

Secondary outcome measures
The following were assessed at baseline, during infusion phase (after week 1 and after week 2) and during capsule phase (after two weeks [end of month 1] and then monthly until the end of month 6):
1. Disease Activity Score (DAS)
2. Rheumatoid Arthritis Disease Activity Index (RADAI)
3. Health Assessment Questionnaire (HAQ)
4. 36-item Short Form health survey (SF-36)

Overall study start date
11/07/2000

Completion date
30/04/2004

Eligibility

Key inclusion criteria
1. Patients at least 19 years of age and should not be older than 85 years
2. Patients suffering from Rheumatoid Arthritis (RA), according to American College of

Rheumatology (ACR) criteria, for at least (>=) 6 months
3. Patients with active RA who meet following criteria:
3.1. >= 6 swollen joints
3.2. >= 6 tender joints
3.3. >= 1 of following criteria:
a. Joint morning stiffness >= 45 minutes
b. Erythrocyte Sedimentation Rate (ESR) >= 28 mm
c. C-Reactive Protein (CRP) >= 20 mg/l (normal range: 0 - 9)
4. No pregnant or breast feeding women allowed; monthly negative pregnancy test in women of reproductive age
5. Participant doesn't have a severe concomitant physical or mental illness
6. Participant has to be able to follow the study procedures
7. No severe malfunctioning of the liver, kidneys, bone marrow, blood clotting system
8. Stable dosages of RA medication for at least 1 month prior to baseline:
8.1. DMARD therapy with methotrexate of at least 10 mg per week over 4 months
8.2. Prednisone <=10 mg daily
9. No injection of glucocorticoids into a joint within 3 month prior to baseline
10. Participant must not have legal conflict
11. Participant must not have alcohol or drug abuse problems
12. Written informed consent signed by the participant

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Known allergy against fish oil or any other substance of the study medication
2. Participant is younger than 19 years of age
3. Patient simultaneously participates in another trial
4. Participant doesn't sign the written informed consent.
5. No stable dosage of RA medication 1 month prior to baseline
6. Injection of glucocorticoids into a joint within 3 month prior to baseline
7. Pregnant or breast feeding women; positive pregnancy test in women of reproductive age
8. Patient has legal conflicts
9. Patient has alcohol or drug abuse problems
10. Severe concomitant physical or mental illness
11. Participant is physically or mentally unable to follow the study procedures
12. Hereditary disorder of lipid metabolism
13. Blood triglyceride levels >300 mg/dl
14. Patients with uncontrolled diabetes mellitus
15. Severe malfunctioning of the liver, kidneys, bone marrow, blood clotting system:
15.1. Creatinin clearance <=30 ml/min
15.2. Elevated levels of ALanine aminoTransferase (ALT) 2 fold above the upper normal range

15.3. Leucopenia <=2,500/ml, red blood cells <=2.5 mill/ml, hemoglobin <=9 mg/dl, platelets <=70,000/ml
16. Severe cardiovascular disease
17. Known neoplasms

Date of first enrolment
11/07/2000

Date of final enrolment
30/04/2004

Locations

Countries of recruitment
Austria

Study participating centre
State Hospital Muerzzuschlag
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Austria
8680

Sponsor information

Organisation
Medical University of Graz (Austria)

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Sponsor type
University/education

Website
http://www.meduni-graz.at/englisch/

ROR
https://ror.org/02n0bts35

Funder(s)

Funder type
Other

Funder Name
Investigator-funded (This trial is a physician initiated study) (Austria)

Funder Name
Fresenius Kabi Austria (Provided Omega-3 infusions only)

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