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# High Intensity Training in patients with rheumatoid arthritis

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 20/05/2008 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 24/07/2008 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 24/07/2008 | Musculoskeletal Diseases | [ ] Record updated in last year |

**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**
N/A

# Study information

## Scientific Title
High Intensity Training in rheumatoid arthritis (RA)-molecular pathways related to inflammation, fatigue and pain

## Acronym
HIT-study

## Study objectives
The overall aim of the present study is to explore the underlying mechanisms of muscle weakness, inflammation, and pain with particular reference to the role of muscle strength in females with early rheumatoid arthritis (RA) by investigating the effects of high-intensity strength training on clinical variables, systemic and local molecular expression, and pathophysiological pain mechanisms.

Specific research questions are:
1. What are the effects of a twelve-week high intensity muscle strength training program on muscle strength, pain, fatigue and general health perception? (Hypothesis I)
2. Can training reduce C-reactive protein (CRP) levels in serum? (Hypothesis II)
3. Can training reduce the number of swollen joints? (Hypothesis II)
4. Can training decrease gene expression of inflammatory molecules in peripheral blood and in muscle tissue? (Hypothesis II)
5. Can training affect the phenotype of peripheral blood cells (of special interest the CD28 null T cells)? (Hypothesis II)
6. Can training have a positive effect on metabolic changes in muscle tissue? (Hypothesis III)
7. Can training affect concentration of reactive oxygen species (ROS) and reduced mitochondrial density in muscle tissue of RA patients? (Hypotheses II and III)
8. Is the expression of oestrogen receptors in muscle tissue different between patients with RA and healthy controls? (Hypothesis IV)
9. Can training alter the expression of oestrogen receptor? (Hypothesis V)
10. Is increased pain sensitivity at baseline related to the intensity of clinical pain? (Hypothesis VI)
11. Do increased pain sensitivity or a dysfunction of endogenous pain inhibitory controls at baseline predict poor treatment outcome following training? (Hypothesis VI)
12. Does training reduce pressure pain sensitivity and improve the function of endogenous pain inhibitory mechanisms? (Hypothesis VI)

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics approval received from the Regional Research Ethics committee, Karolinska Institute, Stockholm on the 10th March 2008 (ref: 2008/243-32 2007/897-31).

## Study design
Single-blind, randomised controlled trial (2 arms)

## Primary study design
Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)
Not specified

## Study type(s)
Quality of life

## Participant information sheet

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

## Interventions
The intervention group will participate in strength training three times a week in a 75-minute training program for 12 weeks. Eight major muscle groups will each be trained in three sets of eight repetitions at approximately 80% of maximum performance and a couple minutes of rest between each set. Each participant's maximum performance will be tested at baseline and every other week thereafter. Every training occasion starts with five minutes of warming up and ends with 10 minutes' cool down. Two weekly training sessions take place in training machines under the supervision of a physiotherapist. One weekly session is performed in the participants' home with the help of an instructive DVD and with their own body weight and rubber bands as resistance.

The control group continues their normal contacts with the health care, which during the time of the intervention does not include strength training. At the end of the intervention they will be offered the same strength training program.

Patients will be followed up for three months for the intervention group and three months for the control group.

## Intervention Type
Other

## Phase
Not Specified

## Primary outcome measure
Static and isokinetic muscle strength in knee extensors and knee flexors measured electronically with the Kin-Com.

Both the primary and the secondary outcomes will be measured at baseline and at three month follow up.

## Secondary outcome measures
1. Clinical outcome (body functions, pain, fatigue and perceived health)
2. Inflammation
3. Pain mechanisms
4. Comorbidity

5. Muscle biopsies from vastus lateralis analysed for reactive oxygen species/reactive nitrogen species and expression of oestrogen receptors in muscles from patients with RA patients and controls before and after the intervention

Both the primary and the secondary outcomes will be measured at baseline and at three month follow up.

### Overall study start date
01/08/2008

### Completion date
01/08/2012

## Eligibility

### Key inclusion criteria
1. Twenty female patients after menopause
2. RA according to American College of Rheumatology criteria
3. Less than 12 months since diagnosis
4. Stable medication since at least three months
5. Independent in daily living
6. Passed menopause
7. Speak and understand Swedish
8. No other major disease that prevent them from performing intensive strength training

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
Twenty females

### Key exclusion criteria
Does not comply with the above inclusion criteria.

### Date of first enrolment
01/08/2008

### Date of final enrolment
01/08/2012

## Locations

### Countries of recruitment
Sweden

**Study participating centre**
**Department of Clinical Science and Education**
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# Sponsor information

**Organisation**
ALF Foundation (Sweden)

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**Sponsor type**
Research organisation

**Website**
http://www.forskningsstod.sll.se

# Funder(s)

**Funder type**
Research organisation

**Funder Name**
ALF Foundation (Sweden) (ref: 20070087 and 20080117)

# 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