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Intramuscular mechanisms underlying work related trapezius muscle pain - physical activity as intervention for rehabilitation

Submission date	Recruitment status	[ ] Prospectively registered
21/02/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/03/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/06/2010	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
KF 01-138/04

Study information

Scientific Title

Acronym
RAMIN (Rehabilitering Af Muskelsmerter I Nakken; Rehabilitating Activity for Myalgia In the Neck)

Study objectives
1. Metabolic and morphological differences exist in the trapezius muscle among female workers with and without neck/shoulder myalgia
2. Physical activity in terms of dynamic resistance training and bicycle training will via different mechanisms relieve pain and modulate muscle metabolism and morphology of the trapezius muscle in female workers with neck/shoulder myalgia

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Local Ethical Committee of Copenhagen, Denmark (ref: KF 01-138/04).

Study design
Case control and randomised cluster balanced interventional trial

Primary study design
Interventional

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Musculoskeletal Disorders

Interventions
Intervention amended as of 22/08/2007:
Participants are randomised to receive one of the following:
1. Dynamic resistance training: 20 minutes per session, three times a week, for 10 weeks supervised by an instructor

2. Leg bicycle training: 20 minutes per session, three times a week, for 10 weeks supervised by an instructor
3. Health promoting information but no physical training

Interventions provided at time of registration:
Participants are randomised to receive one of the following:
1. Dynamic resistance training
2. Leg bicycle training
3. Health promoting information but no physical training

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Primary outcome measures amended as of 22/08/2007:
The following will be assessed at baseline before the intervention and again immediately after the 10-week intervention training:
1. Perceived pain
2. Clinical findings
3. Muscle strength and function

Primary outcome measures provided at time of registration:
1. Perceived pain
2. Clinical findings
3. Muscle strength and function

Secondary outcome measures
Secondary outcome measures amended as of 22/08/2007:
The following will be assessed at baseline before the intervention and again immediately after the 10-week intervention training:
1. Muscle biochemistry and histochemistry
2. Microdialysis
3. Ultrasound
4. Electromyography (EMG)
5. Near infrared spectroscopy (NIRS)
6. Exercise test performance

Secondary outcome measures provided at time of registration:
1. Muscle biochemistry and histochemistry
2. Microdialysis
3. Ultrasound
4. Electromyography (EMG)
5. Near infrared spectroscopy (NIRS)
6. Exercise test performance

Overall study start date
01/08/2005

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Generally healthy female workers
2. Aged 30 - 60 years
3. With and without trapezius myalgia

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
20 without and 60 with trapezius myalgia

Key exclusion criteria
1. Trauma
2. Generalised muscle pain
3. Life threatening diseases

Date of first enrolment
01/08/2005

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Denmark

Study participating centre
National Research Centre for the Working Environment
Copenhagen
Denmark
DK-2100

Sponsor information

Organisation
The National Research Centre for the Working Environment (Denmark)

Sponsor details
Lersø Parkalle 105
Copenhagen Ø
Denmark
DK 2100

Sponsor type
Government

Website
http://www.arbejdsmiljoforskning.dk/

ROR
https://ror.org/03f61zm76

Funder(s)

Funder type
Government

Funder Name
Danish Medical Research Council (Denmark) (ref: 22-03-0264)

Funder Name
The Danish Rheumatism Association (Denmark) (ref: 233-1149-02.02.04)

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	15/01/2008		Yes	No
Results article	results	01/06/2010		Yes	No