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 [] Statistical analysis plan Registration date Overall study status 14/03/2007 Completed [X] Results [] Individual participant data Last Edited Condition category 11/06/2010 Musculoskeletal Diseases

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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

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