ISRCTN35925199 https://doi.org/10.1186/ISRCTN35925199

The effect of physical activity interventions on inflammatory muscle disorders

Submission date
05/05/2020

Recruitment status
No longer recruiting

Registration date
22/05/2020

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Idiopathic inflammatory myopathies are diseases characterized by muscle weakness, caused by inflammation and atrophy in the affected muscles, which lead to a limitation in the execution of daily activities. The aim of this study is to investigate the impact of specialized activities of daily living (ADL) training on muscle strength and endurance, function, quality of life, and other selected aspects specific to this disease.

Who can participate?
Adult patients with myositis who are routinely followed and treated at the Institute of Rheumatology in Prague (Czech Republic)

What does the study involve?
Participants are allocated into the intervention or control group based on their willingness to adhere to the schedule. The control group receive standard care (i.e. standard drug treatment and materials for regular daily home exercise focused on activities of daily living). The intervention group receive standard care (as described above) and 6 months of a specialized intervention program twice a week consisting of supervised physiotherapy (1 hour focused on activities of daily living and 1 hour focused on muscle strengthening). Participants are assessed before the start of the study), week 12 (i.e. after half of the 6-month intervention), week 24 (i.e. after the end of the 6-month intervention), and week 48 (i.e. after the end of a 6-month follow-up).

What are the possible benefits and risks of participating?
Patients in the intervention group may benefit from the intensive supervised physiotherapy program by improving their muscle strength/endurance or function in general, and patients in both groups may benefit from more detailed examinations by healthcare professionals during the course of the study. Potential risks should be eliminated by the tailored modification of the intensity of the physiotherapy program which will be adapted to the actual level of general health and function of each patient.

Where is the study run from?
Institute of Rheumatology (Czech Republic)

When is the study starting and how long is it expected to run for?
May 2014 to June 2017

Who is funding the study?
Czech Ministry of Health (Czech Republic)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effectiveness of specialized activities of daily living training in patients with idiopathic inflammatory myopathies

Acronym
ADL-IIM

Study objectives
A specialized, long-term, tailored, physiotherapy program focused on activities of daily living in patients with idiopathic inflammatory myopathies improves the muscle, strength, endurance, overall function, disability, quality of life, fatigue, depression, stability (compared to controls treated with the standard of care) and is safe (does not increase systemic or local levels of inflammatory markers).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/07/2014, Ethics Committee of the Institute of Rheumatology (Na Slupi 4, 128 50 Praha 2, Czech Republic; +420 (0)234075244; putova@revma.cz), ref: 1446/2014

Study design
interventional single-centre prospective non-randomized controlled trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Idiopathic inflammatory myopathies/myositis

Interventions
Patients are allocated into the intervention or control group based on their willingness to adhere to the schedule.

Control group: standard of care (i.e. standard pharmacological treatment according to the recommendations of the leading experts in the field on the management of idiopathic inflammatory myopathies, education, and materials for regular daily home exercise focused on activities of daily living)

Intervention group: standard of care (as described above) + 6 months of specialized intervention program twice a week consisting of supervised physiotherapy (1 hour focused on activities of daily living and 1 hour focused on muscle strengthening)

Outcomes measured at baseline (i.e. week 0, before the start of the study), week 12 (i.e. after half of the 6-month intervention), week 24 (i.e. after the end of the 6-month intervention), and week 48 (i.e. after the end of a 6-month follow-up)

Intervention Type
Behavioural

Primary outcome measure
1. Muscle endurance assessed by FI-2 test (Functional Index-2)
2. Muscle strength assessed by MMT8 test (Manual Muscle Testing-8)

Measured at baseline (i.e. week 0, before the start of the study), week 12 (i.e. after half of the 6-month intervention), week 24 (i.e. after the end of the 6-month intervention), and week 48 (i.e. after the end of a 6-month follow-up)

Secondary outcome measures
1. Health/disability assessed using HAQ questionnaire (Health Assessment Questionnaire)
2. Quality of life assessed using SF-36 questionnaire (Medical Outcomes Short Form-36)
3. Fatigue assessed using FIS questionnaire (Fatigue Impact Scale)
4. Depression assessed using BDI-II questionnaire (Beck´s Depression Inventory-II)
5. Stability assessed by stabilometry - vector trace area
6. Body composition assessed by bioelectric impedance (BIA-2000-M) and densitometry (iDXA Lunar)
7. Safety assessed using local (in the muscle biopsy samples extracted before the start and after the end of the intervention program) and systemic expression of selected inflammatory markers

Measured at baseline (i.e. week 0, before the start of the study), week 12 (i.e. after half of the 6-month intervention), week 24 (i.e. after the end of the 6-month intervention), and week 48 (i.e. after the end of a 6-month follow-up)

Overall study start date
01/05/2014

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. An Independent Ethics Committee approved written Informed Consent form is signed and dated by the subject
2. Participant is considered reliable and capable of adhering to the protocol and visit schedule
3. Participant is male or female at least 18 years of age
4. Participant fulfilled the Bohan/Peter 1975 criteria (for polymyositis and dermatomyositis) or the ENMC 2004 criteria (for immune-mediated necrotizing myopathy)
5. Participant must have a weakness of proximal muscle groups
6. Participant is regularly followed at our out-patient department and adheres to the standard-of-care pharmacological therapy indicated by his treating rheumatologist
7. Participant is willing to participate in the study and undergo all planned examinations

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20 patients in the intervention group, 20 patients in the control group

Total final enrolment
52

Key exclusion criteria
Participant has any other condition, including medical or psychiatric, which in the investigator's judgment would make the subject unsuitable for inclusion in the study

Date of first enrolment
01/01/2015

Date of final enrolment
01/04/2016

Locations

Countries of recruitment
Czech Republic

Study participating centre
Institute of Rheumatology
Na Slupi 4
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Sponsor information

Organisation
Revmatologický ústav

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Sponsor type
Hospital/treatment centre

Website
http://www.revma.cz

ROR
https://ror.org/00jk0vn85

Funder(s)

Funder type
Government

Funder Name
Ministry of Health Czech Republic (grant nr. 16-33574A)

Funder Name
Project for Conceptual Development for the institution of Ministry of Health Czech Republic - Institute of Rheumatology (number 023728)

Results and Publications

Publication and dissemination plan
Planning to publish the results in a rheumatology-oriented peer-reviewed journal with an impact factor.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/06/2021	24/06/2021	Yes	No
Results article		28/09/2022	14/06/2023	Yes	No