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The effects of vigorous exercise training on motor function and functional fitness in juvenile arthritis

Submission date
14/03/2007

Recruitment status
No longer recruiting

Registration date
14/03/2007

Overall study status
Completed

Last Edited
19/11/2009

Condition category
Musculoskeletal Diseases

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

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
NCT00213187

Secondary identifying numbers
MCT-75507

Study information

Scientific Title
The effects of vigorous exercise training on motor function and functional fitness in juvenile arthritis: a single blind randomised controlled trial

Acronym
PEAK

Study objectives
A rigorous 12-week aerobic exercise training program is more effective in improving metabolic efficiency (in terms of oxygen cost of locomotion) than a gentle Qigong exercise program.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Board of the Hospital for Sick Children (Canada) approved on the 13th August 2002 (initially), 11th August 2006 (second) (ref: 0020020201).

Study design
Two-arm single centre randomised parallel trial with outcome assessor blinding

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Juvenile idiopathic arthritis

Interventions
Treatment group: a 12-week vigorous aerobic exercise program
Control group: a 12-week Qi gong exercise program

Contact for public queries:
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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Improved metabolic walking efficiency (measured by oxygen consumption) at baseline (week zero) and completion of trial (week 12)

Secondary outcome measures
1. Maximal aerobic capacity at week zero and 12
2. Anaerobic endurance and peak muscle power at week zero and 12
3. Physical function at week zero and 12
4. Quality of life at week zero and 12
5. Safety testing at week zero and 12
6. Arthritis activity (pain) from week zero through to 12
7. Range of motion at week zero and 12
8. Heart rate monitoring from week zero through to 12
9. Ratings of Perceived Exertion (RPE) from week zero through to 12
10. Anthropometry at week zero and 12
11.Comfortable walking speed at week zero and 12
12. Acceptability of exercise training (qualitative questionnaire) upon completion of program at week 12

Overall study start date
01/03/2003

Completion date
01/09/2005

Eligibility

Key inclusion criteria
1. Aged eight to 16 years, either sex
2. Diagnosis of juvenile idiopathic arthritis
3. Stable disease - on a stable dose of non-steroidal anti-inflammatory drugs (NSAID), if applicable methotrexate or other second line agents - in the preceding month, and judged by the rheumatologist to be clinically stable over the course of the trial
4. Medications: there are no restrictions on medication use for this study, however, every effort is made to keep medication dose stable over the course of the study

Participant type(s)

Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Co-morbidity with cardiac, pulmonary, or metabolic disease
2. Moderate or severe hip pain while walking (as judged by the patient and scored on a four point scale)
3. Active systemic symptoms (fever or rash)
4. Children who engaged in three or more hours of extracurricular physical activity weekly
5. Children who are unable to cooperate with testing procedures

Date of first enrolment
01/03/2003

Date of final enrolment
01/09/2005

Locations

Countries of recruitment
Canada

Study participating centre
The Hospital for Sick Children
Ontario
Canada
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Sponsor information

Organisation

The Hospital for Sick Children (Canada)

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Sponsor type
Hospital/treatment centre

Website
http://www.sickkids.ca/

ROR
https://ror.org/057q4rt57

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca/ (ref: MCT-75507)

Funder Name
The Arthritis Society (Canada)

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	15/10/2007		Yes	No