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The effect of exercise on fasting insulin and fitness levels in people with spinal cord injury: Development of evidence-based exercise programs

Submission date
24/05/2017

Recruitment status
No longer recruiting

Registration date
31/05/2017

Overall study status
Completed

Last Edited
30/05/2017

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Individuals with spinal cord injury generally have a sedentary (inactive) lifestyle, which negatively impacts their fitness level and quality of life. Moreover, those with SCI are at increased risk of developing long-term health conditions such as type 2 diabetes, heart disease and metabolic syndrome (a group of conditions which increase a person's risk of heart attack or stroke). Therefore, promoting an active lifestyle for those with SCI is important for the prevention of these diseases. The aim of this study are to assess the effects of personalized exercise programs on insulin (the hormone which converts sugar in the blood into stored sugars) and fitness levels of people with spinal cord injury.

Who can participate?
Patients with Spinal cord injury

What does the study involve?
Patients are randomly allocated to either the exercise group or the control group. Those in the exercise group receive a six-week combined exercise program. Participants will exercise for 60 minutes per session, three times per week for six weeks. The daily exercise programs consist of a 25-minute warm up consisting of 5 min of joint exercises, 15 min of exercise on an arm ergometer, and 5 min of stretching, followed by a 30-minute exercise program (resistance, circuit, and aerobic training), and a 5-minute cool down (stretching). Those in the control group are instructed to continue with their usual daily activities. At the start of the study and after six weeks, participants in both groups provide blood samples to assess their insulin and blood sugar levels, and complete questionnaires about their quality of life and mood. In addition. participants have their fitness levels assessed.

What are the possible benefits and risks or participating?
Participants allocated to the exercise group will receive the thera-band, and results of clinical tests. There are no known risks to participants.

Where is the study run from?
Fitness Center, Yonsei University (South Korea)

When is the study starting and how long is it expected to run for?
April 2014 to December 2014

Who is funding the study?
National Rehabilitation Research Institute (South Korea)

Who is the main contact?
1. Professor Justin Jeon (scientific)
2. Dr Dong-Il Kim (public)

Contact information

Type(s)
Scientific

Contact name
Prof Justin Y Jeon

Contact details
Yonsei University
134 Shinchon-Dong
Seodaemun-Gu
Seoul
Korea, South
120-749

Type(s)
Scientific

Contact name
Dr Dong-Il Kim

Contact details
Yonsei University
Department of Sport and Leisure Studies
50 Yonsei-Ro, Seodaemun-Gu
Seoul
Korea, South
120-749

Additional identifiers

Protocol serial number
1040917-201404-HRBR-152-03

Study information

Scientific Title
A randomized controlled trial of six-weeks combined exercise program on fasting insulin and fitness levels in individuals with spinal cord injury

Study objectives
A six-week combined exercise program will improve on fasting insulin and fitness levels in individuals with spinal cord injury.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Review Board at Yonsei University College of Medicine, 04/04/2014, ref: 1040917-201404-HRBR-152-03

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Spinal cord injury

Interventions
Participants will be randomized to one of two groups using the minimization method.

Intervention group: Participants will receive a 6-week combined exercise program. Participants will exercise for 60 minutes per session, three times per week for six weeks. The daily exercise programs consist of a 25-minute warm up consisting of 5 min of joint exercises, 15 min of exercise on an arm ergometer, and 5 min of stretching, followed by a 30-minute exercise program (resistance, circuit, and aerobic training), and a 5-minute cool down (stretching).

Control group: Participants will be instructed to continue with their usual daily activities.

Participants in both groups will be followed up after six weeks.

Intervention Type
Other

Primary outcome(s)
1. Fasting glucose is measured using ADVIA 1650 Chemistry System at baseline and six weeks
2. Insulin is measured using Roche Chemistry System at baseline and six weeks
3. Insulin resistance will be estimated according to the homeostasis model assessment of insulin resistance (HOMA-IR) index at baseline and six weeks

Key secondary outcome(s))

1. Total cholesterol (TC), triglyceride (TG), high density lipoprotein cholesterol (HDL-C), and low density lipoprotein cholesterol (LDL-C) levels will be measured using an ADVIA 1650 Chemistry System at baseline and six weeks
2. Upper body strengh will be measured by a hand-held dynamometer at baseline and six weeks
3. Vo2 peak will be assessed through maximal graded exercise tests, performed using a ramp protocol at baseline and six weeks.
4. Quality of life will be measured using the SF-36 questionnaire at baseline and six weeks
5. Anxiety and depression will be measured using the Generalized Anxiety Disorder 7-item (GAD-7) scale and Patient Health Questionnaire (PHQ-9) at baseline and six weeks

Completion date
22/12/2014

Eligibility

Key inclusion criteria
1. An SCI >6 months
2. Age between 18 and 65 years
3. No regular exercise over the prior six months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Cardiovascular disease
2. Uncontrolled type 2 diabetes
3. Uncontrolled hypertension
4. Pressure ulcers
5. Orthopedic problems

Date of first enrolment
04/04/2014

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
Korea, South

Study participating centre
Yonsei University College of Medicine
134 Shinchon-Dong
Seodaemun-Gu
Seoul
Korea, South
120-749

Sponsor information

Organisation
Yonsei University

ROR
https://ror.org/01wjejq96

Funder(s)

Funder type
Research organisation

Funder Name
National Rehabilitation Research Institute

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from hiop1@hanmail.net

IPD sharing plan summary
Not provided at time of registration