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Regular resistance training in children with type 1 diabetes improves glycaemic control and physical fitness

Submission date
09/08/2018

Recruitment status
No longer recruiting

Registration date
30/08/2018

Overall study status
Completed

Last Edited
08/11/2019

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The incidence of insulin-dependent diabetes mellitus (type 1 diabetes) has increased especially in children and adolescents under the age of 15. Exercise has been accepted and generally recommended for the management of type 1 diabetes. Young people generally prefer to use gyms for resistance training; however, there is unfortunately a lack of information on resistance training in children with type 1 diabetes. This study aims to look at the effects of supervised resistance training in children with type 1 diabetes.

Who can participate?
Children aged 8-12 with type 1 diabetes, diagnosed at least 6 months before the study

What does the study involve?
Children participating in this study will be randomised into either the intervention or the control group. Children in the intervention group will participate in a 32 week program of resistance training, with a 50 minute session twice per week. Children in the control group will continue as usual. Both groups will be asked to undertake various measurements at the start and end of the 32 week intervention, including height, weight, exercise and strength tests and blood tests.

What are the possible benefits and risks of participating ?
The possible benefit of participating is that taking part in the exercise intervention should result in an improvement of physical fitness and in control of their diabetes. There are no known risks to participants taking part in this study, other than possible hypoglycaemia. However, blood glucose will be determined before and after each exercise session to monitor this and prevent hypoglycaemia.

Where is the study run from?
Department of Pediatrics, Department of Chemistry and the Institute of Physical Medicine and Rehabilitation at the Danube Hospital Vienna (Austria)

When is the study starting and how long is it expected to run for?
August 2013 to April 2015

Who is funding the study?
City Government of Vienna (Austria)

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
EK-13-175-0813

Study information

Scientific Title
The effect of a 32 weeks intervention period of supervised progressive resistance training on glycaemic control, physical fitness and adiponectin in children with type 1 diabetes

Acronym
N/A

Study objectives

We hypothesized, that similar to endurance training, regular progressive resistance training in children with type 1 diabetes improves HbA1c levels and physical fitness. Additionally, we hypothesized that progressive resistance has a positive effect on adiponectin levels.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board of the City Goverment of Vienna, 08/10/2013, EK 13- 175-0813

Study design
Interventional single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Type 1 diabetes mellitus

Interventions
Participants were randomised using simple randomisation with Excel into 2 groups, an intervention group and a control group.
At the beginning of the study, participants in both groups performed a standardised, self-paced 6-minute walk test (6MWT) in a corridor of 30 m in length. Strength was assessed using 3 common multi-joint exercises (seated bench press, seated bench pull and a seated leg press). Blood samples were then collected from all participants in the morning after fasting. Echocardiograms were performed to investigate the left common carotid artery.
Participants in the intervention group performed progressive resistance training twice a week for 32 weeks. This involved a circuit exercise programme with 8 stations. Each session lasted for 50 minutes, comprising a 10 minute warm-up, 20-40 minutes of circuit training and cool-down routine for the remainder of the time. Work time was increased and rest time was decreased according to the training load progression principle.
The control group received no intervention and continued their normal daily activities.
At the end of the intervention, the same tests and examinations as at the start of the study were performed for both groups.

Intervention Type
Device

Primary outcome measure
The following were assessed at the baseline and at the end of the intervention (32 weeks):
1. HbA1C levels, assessed through analysis of venous blood samples
2. Physical fitness, assessed using:
2.1. 6-minute walking/running test (GMWT) in a corridor of 30 metres in length
2.2. Strength test including a seated bench press, seated bench pull and seated leg press, assessed using a dynamometer

Secondary outcome measures
The following were assessed at the baseline and at the end of the intervention (32 weeks):
1. Adiponectin levels, assessed through ELISA analysis of blood samples
2. Intima-media thickness (IMT - defined as the distance between the leading edges of the lumen-intima interface and the media-adventitia interface of the far wall), assessed through a scan of the left common carotid artery

Overall study start date
28/08/2013

Completion date
28/04/2015

Eligibility

Key inclusion criteria
1. Type 1 diabetes for at least 6 months
2. No contraindications for participation in a physical activity programme
3. Mixed split-dose insulin regimen
4. No current or recent illness
5. No current or recent operation or injury
6. No participation in regular sport
7. Sports lessons in school less frequently than twice a week

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
29

Key exclusion criteria
N/A

Date of first enrolment
30/06/2014

Date of final enrolment
22/08/2014

Locations

Countries of recruitment
Austria

Study participating centre
Only one centre Danube Hospital
Langobardenstrasse 122
Vienna
Austria
1220

Sponsor information

Organisation
Medical scientific fund of the city of vienna- ethics committee of the city of vienna

Sponsor details
Thomas Klestil Platz 8
Vienna
Austria
1030

Sponsor type
Government

Funder(s)

Funder type
Not defined

Funder Name
This project was supported, in part, by grants from the City Government of Vienna.

Results and Publications

Publication and dissemination plan

We intend to publish in the Journal of Diabetes Care as soon as possible.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
Data will be shared in tabular form. All participants were informed comprehensively about purpose, procedures, benefits, risks and discomfort that might result from study participation, as well as the right to terminate participation at will, before they gave written consent to participate in the study. A letter of agreement had to be signed by the participant's parents or guardians and all participants took part voluntarily. The parents also agreed that the results could be published in anonymous form. Participants were identified by a number code. The number code was known only to the head of the study.

IPD sharing plan summary
Available on request