

Physical activity and physical fitness in children after Orthotopic Liver Transplantation aged 6 -1 2 years

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Primary objective is to compare physical activity (time spent in moderate to vigorous activity and physical activity level) and exercise capacity (VO2 peak) in children after OLT with published data of healthy controls. Secondary objective is to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational non invasive

Summary

ID

NL-OMON40982

Source

ToetsingOnline

Brief title

physical activity and fitness after OLT

Condition

- Hepatic and hepatobiliary disorders

Synonym

physical activity liver transplantation

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: stichting Beatrixkinderziekenhuis

Intervention

Keyword: paediatric liver transplantation, physical activity, physical fitness

Outcome measures

Primary outcome

Physical activity as assessed by 7 days activity monitoring using an Actical accelerometer and an activity diary

Aerobic exercise capacity (VO₂ peak) as assessed during a graded exercise test with respiratory gas analysis

Secondary outcome

Muscle strength as assessed with a hand-held dynamometry

Health related quality of life and fatigue as assessed with the Paediatric

Quality of Life Inventory (PedsQL)

Pain (general) as assessed with the 10 centimeter Visual Analogue Scale (VAS)

Anthropometry (weight, height, fat free mass)

Participation as assessed by the Children's Assessment of Participation and

Enjoyment (CAPE)

Study description

Background summary

Children after Orthotopic Liver Transplantation (OLT) show a survival rate of 88% after 5 years, but this is accompanied by important co-morbidities such as hypertension, atherosclerosis, reduced growth, obesity, lowered bone density, osteoporosis, delayed motor development, increased cardio-vascular risk factors and a lower exercise capacity.

Co-morbidities have to be reduced in order to improve the outcome in these children. Most of the co-morbidities might be related to a lower level of

physical activity. One study published in 2001(1) showed a lower exercise capacity in children (aged 10 and older) after OLT compared to matched controls. However, since 2000, anti-rejection treatment after OLT has changed importantly. The dose of corticosteroids has decreased and immune suppressors with less side effects have been introduced. Following these changes there is no documented evidence as to the affect on children*s activity levels post OLT.

Lower activity levels (and the associated complications/co-morbidity) in children may play a crucial role in the survival rates for children post OLT. Studies in infants with chronic diseases and hart-lung transplants have found that these infants have a lower then normal activity level and as second outcome parameter, a lower exercise capacity. A lower activity level is correlated with complications like overweight and hypertension. This study will investigate if infants with an OLT also have a lower activity pattern compared to published data of healthy children.

Study objective

Primary objective is to compare physical activity (time spent in moderate to vigorous activity and physical activity level) and exercise capacity (VO2 peak) in children after OLT with published data of healthy controls.

Secondary objective is to compare muscle strength, health related quality of life / fatigue, pain, participation and body composition with published data of healthy controls.

Study design

Cross-sectional study

Study burden and risks

Extent of the burden:

Measurements will be combined with a regular visit to the outpatient clinic of the OLT Group. All efforts will be made to combine these measurements with regular controls in our hospital. During the visits an aerobic exercise test will be conducted. This is a well known test without risks for the child and takes 45 minutes (the test itself 10 minutes). Testing of all the parameters takes about one hour and 45 minutes in the hospital. At home children wear an accelerometer for a week and fill in an activity diary. Filling in the diary will cost approximately 15 minutes a day. Parents have to fill in two questionnaires in the hospital which takes 10 minutes.

Risk:

Neither of these measures are related to increased risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Post OLT (more than one year)
age 6-12 years
good functioning liver (normal PT, Bilirubine, Albumine)
Being able to follow test instructions
parental consent and child assent (12 years)

Exclusion criteria

Medical event that might intervene with the outcome of testing (other than associated with OLT) for instance recent trauma/fracture and secondary diagnosis like down syndrome.

Medical status that will not allow maximal exercise testing (e.g. acute fever, heart conditions).

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 06-02-2015

Enrollment: 26

Type: Actual

Ethics review

Approved WMO

Date: 16-06-2014

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register

CCMO

ID

NL48571.042.14