# Effects of exercise on the immune system in pediatric acute lymphoblastic leukemia (ALL) patients.

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What is the effect of different bouts of exercise on the immune system in patients with acute lymphoblastic leukemia?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Leukaemias
Study type	Interventional

### **Summary**

### ID

NL-OMON36567

**Source** ToetsingOnline

Brief title Exercise and Immunology in ALL (ExImA)

### Condition

Leukaemias

**Synonym** Cancer of the blood

**Research involving** Human

### **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Utrecht **Source(s) of monetary or material Support:** KIKA

### Intervention

Keyword: Children, Immunology, Leukemia, Physical exercise

### **Outcome measures**

#### **Primary outcome**

The main study parameter is the change in inflammatory markers before and after

different bouts of exercise.

#### Secondary outcome

Correlation between exercise-induced change in inflammatory markers and

physical fitness (VO2peak)

• Correlation between changes in inflammatory markers (e.g NK cells, IL-6,

IL-8, IL-10, C-reactive protein and TNF- $\alpha$ ) and neutrophil function.

• Difference in enjoyment between the 3 different exercise training sessions

# **Study description**

#### **Background summary**

Leukemia accounts for 30% of cancer in children 0 to 14 years and 25% of cancers occurring before age 20. Acute lymphoblastic leukemia (ALL) is the most common childhood cancer. Chemotherapy treatments for ALL cause immunosuppression, leading to an increase in susceptibility to infections, requiring reconstitution of immune function after treatment. Literature pertaining to the relationship between risk of infection and physical activity is sparse, but for the general population of healthy active children, increased levels of physical activity are associated with reduced susceptibility to respiratory infections. In contrast, the available evidence in adults suggests that high volume sport training can increase the susceptibility to illness and infection.

Exercise scientists have been investigating, for some time, how acute and

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chronic exercise might influence the immune system\*s ability to combat infection and illness. Despite the proliferation of this field, however, there remains a paucity of studies devoted to the pediatric population. Consequently, very little is known regarding the interactions of acute and chronic exercise and the immune system in children and adolescents and their implications for health and disease.

There is substantial evidence to show that physical exercise can produce desirable changes in the distribution and function of cellular and humoral components of the immune system in healthy children and adolescents. Moreover, current research shows that physical training becomes more important in the rehabilitation of children and adults with cancer and survivors. More evidence on the acute and chronic effects of exercise in this population is needed to establish the safety of exercise and its optimum to rule out adverse effects of exercise on the compromised immune system of children with cancer. In short, therapeutic advances have created an increasing number of childhood survivors of cancer. For these children, physical activity is beneficial, but only if the \*exercise dose\* does not exacerbate the inflammatory status abnormalities. Identifying \*optimal\* levels and safe limits of exercise training must be based on a better understanding of the mechanisms that link exercise as a therapeutic tool with the health benefits in the growing child with cancer.

#### **Study objective**

What is the effect of different bouts of exercise on the immune system in patients with acute lymphoblastic leukemia?

#### Study design

This study is a intervention study in children with ALL.

#### Intervention

Three different bouts of exercise: cycle ergometer test, active computer game and physical therapy session

#### Study burden and risks

Participants will be asked to perform a graded maximal exercise test to measure VO2peak (session 1) and to take part in three exercise sessions (session 2-4) that will last approximately 1 hour. They will be asked to fill out a physical exercise enjoyment scale after each session and a habitual physical exercise questionnaire once. To measure the habitual physical exercise objectively, the children wil carry an accelerometer (Actical) attached to their belt during a week

The level of discomfort should be minimal as all of these sessions are safe for children to perform. They may experience some muscle soreness or stiffness, but this should not worsen their disease or disability. During the three exercise sessions blood samples will be collected at 3 time points: pre-exercise, post-exercise, and 1-hour post-exercise. In total 9 blood samples will be taken from each participant, in which only three times we need to insert an entry to draw blood. Most of the children with ALL do have a port-a-cath (PAC). All the collections will be performed by M Kruijsen-Jaarsma, MD. Anthropometric measurements consist of weight, length and three skin fold measurements. The risks and side-effects of the exercise will be minimal. Moreover, the physical exercise has also a lot of benefits: exercise can improve aerobic fitness and improve health related quality of life. Drawing blood is an intervention that will not be seen as minimal.

## Contacts

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adolescents (12-15 years) Adolescents (16-17 years)

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Children (2-11 years)

### **Inclusion criteria**

•Diagnosis of Acute lymphoblastic leukemia (ALL) with a port-a-cath - medium risk, based on DCOG ALL 10 protocol.

•Sufficiently healthy to participate

•A minimal body mass of 25 kg will be required, in order to allow repeated blood sampling

#### **Exclusion criteria**

• Down syndrome or children with multiple morbidity

Non-ambulation: patients who are unable to ambulate or who will not be able to complete any part of the study protocol due to the severe physical limitations will be excluded
Unable to cooperate with testing procedures (e.g. insufficient understanding of Dutch language)

# Study design

### Design

Study type: Interventional	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

### Recruitment

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NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	25-02-2011
Enrollment:	20
Туре:	Actual

### **Ethics review**

#### Approved WMO

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Date:	11-03-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-09-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

# **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 NL29284.041.09