

The effect of physiotherapy on development, extent and duration of motor problems in children with acute lymphoblastic leukaemia

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 19/12/2008	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Annelies Hartman

Contact details
Erasmus Medical Centre
Sophia Children's Hospital
Department of Paediatric Physiotherapy
P.O. Box 2060
Amsterdam
Netherlands
3000 CB
j.hartman@erasmusmc.nl

Additional identifiers

Protocol serial number
NTR251

Study information

Scientific Title

Study objectives

Physiotherapy will diminish the development, extent and duration of motor problems in children with acute lymphoblastic leukaemia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Primary study design

Interventional

Study design

Randomised single-blind active controlled parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute lymphoblastic leukaemia (ALL)

Interventions

Children who are randomised to the physiotherapy group receive a standardised exercise program, which starts in week 1 of their chemotherapy treatment, is carried out at home and monitored by a physiotherapist.

Children who are randomised to the control group, only receive physiotherapy if motor problems occur. This is current standard practice.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Motor performance is measured with the Motor Assessment Battery for Children - a standardised test for motor performance - at the onset of chemotherapy, after six weeks, one year after starting chemotherapy and on completion of therapy.

Key secondary outcome(s)

Objective signs of polyneuropathy, i.e. decreased reflexes, sensory disturbance and muscle weakness are assessed.

Completion date

01/10/2006

Eligibility

Key inclusion criteria

Children aged 1 - 18 years diagnosed with acute lymphoblastic leukaemia

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

1 Years

Upper age limit

18 Years

Sex

All

Key exclusion criteria

1. Additional medical conditions known to have an effect on motor development
2. Cognitive impairment

Date of first enrolment

01/03/2001

Date of final enrolment

01/10/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Erasmus Medical Centre

Amsterdam

Netherlands

3000 CB

Sponsor information

Organisation

Erasmus Medical Centre (Netherlands)

ROR

<https://ror.org/018906e22>

Funder(s)**Funder type**

Research organisation

Funder Name

Erasmus Medical Centre (The Netherlands) - Revolving Fund

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration