

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/12/2008	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Randomised single-blind active controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/03/2001

Completion date

01/10/2006

Eligibility**Key inclusion criteria**

Children aged 1 - 18 years diagnosed with acute lymphoblastic leukaemia

Participant type(s)

Patient

Age group

Child

Lower age limit

1 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

52

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)

Sponsor details

Sophia Children's Hospital

Dr. Molewaterplein 60

Rotterdam

Netherlands

3015 GJ

Sponsor type

Hospital/treatment centre

Website

<http://www.erasmusmc.nl/content/englishindex.htm>

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

Erasmus Medical Centre (The Netherlands) - Revolving Fund

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration