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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 19/12/2008	**Condition category** Cancer	

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

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

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