

Gepubliceerd: 07-09-2005 Laatste bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

Bron

NTR

Verkorte titel

N/A

Aandoening

Acute lymphoblastic leukaemia.

Ondersteuning

Primaire sponsor : -

Overige ondersteuning : Revolving Fund, Erasmus MC, Rotterdam, The Netherlands.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

Children diagnosed with acute lymphoblastic leukaemia are randomised to a physiotherapy (PT) group or to a control group.

Children who are randomised to the PT 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. Motor performance of the children is measured at the onset of chemotherapy, after six weeks, one year after starting chemotherapy, on completion of chemotherapy.

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

The assessor is kept blind to the group to which the children are randomised.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Erasmus Medical Center, Sophia Children's Hospital, Department of Pediatric Physiotherapy,
P.O. Box 2060
Annelies Hartman
Amsterdam 3000 CB
The Netherlands

Wetenschappelijk

Erasmus Medical Center, Sophia Children's Hospital, Department of Pediatric Physiotherapy,
P.O. Box 2060
Annelies Hartman
Amsterdam 3000 CB
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Children, aged 1-18 years diagnosed with acute lymphoblastic leukaemia.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Additional medical conditions known to have an effect on motor development;

2. Cognitive impairment.

Onderzoeksopzet

Opzet

Type :	Interventie onderzoek
Onderzoeksmodel :	Parallel
Toewijzing :	Gerandomiseerd
Blindering :	Enkelblind
Controle :	Geneesmiddel

Deelname

Nederland	
Status :	Werving gestopt
(Verwachte) startdatum :	01-03-2001
Aantal proefpersonen :	52
Type :	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum :	07-09-2005
Soort :	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL213
NTR-old	NTR251
Ander register	: N/A
ISRCTN	ISRCTN63483122

Resultaten

Samenvatting resultaten

N/A