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Protocol for treatment and research of acute lymphoblastic leukaemia of childhood of the Dutch childhood oncology group

Submission date 28/02/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/02/2007	**Overall study status** Completed	
Last Edited 20/08/2021	**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
SNWLK/DCOG ALL-9

Study information

Scientific Title
Protocol for treatment and research of acute lymphoblastic leukaemia of childhood of the Dutch childhood oncology group

Study objectives
The dutch ALL-6 protocol (1984 - 1988) for standard risk childhood Acute Lymphoblastic Leukaemia (ALL) was one of the first to use dexamethasone as a steroid instead of prednisone. This led to surprisingly good results. The ALL-9 protocol thus was meant to reproduce these results and to extend the use to patients with high risk ALL.

This reduced intensity protocol is instituted to:
1. Confirm the data obtained in the SNWLK-ALL-6 protocol for standard risk patients
2. Offer significant improvement of cure rate in high risk patients, comparable to international childhood ALL protocols
3. Offer the possibility to conduct window studies with monotherapy
4. Validate the prognostic significance of in vitro drug resistance testing
5. Standardise the minimal residual disease test
6. Evaluate the side effects, especially osteonecrosis and psychological effects of dexamethasone

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Multicentre, non-randomised, non-controlled, clinical trial

Primary study design
Interventional

Secondary study design
Multi-centre

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute Lymphoblastic Leukaemia (ALL)

Interventions
Stratification into standard risk and high risk.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Dexamethasone

Primary outcome measure
Survival

Secondary outcome measures
Event free survival

Overall study start date
01/01/1997

Completion date
30/10/2004

Eligibility

Key inclusion criteria
All children with acute lymphoblastic leukaemia from one year (365 days) until 18 years of age, excluding mature B-cell ALL.

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Years

Upper age limit
18 Years

Sex
Not Specified

Target number of participants
918

Key exclusion criteria
1. Mature B-cell ALL
2. Relapsed ALL
3. Secondary ALL

4. Pretreatment with corticosteroids or cytostatic drugs in the four weeks preceding diagnosis
5. Patient of whom essential diagnostic tests are missing
6. Patients in whom essential parts of therapy were not given

Date of first enrolment
01/01/1997

Date of final enrolment
30/10/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
Dutch Childhood Oncology Group (Stichting Kinder Oncologie [SKION])
Den Haag
Netherlands
2545 CJ

Sponsor information

Organisation
Dutch Childhood Oncology Group (Stichting Kinder Oncologie [SKION]) (The Netherlands)

Sponsor details
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Sponsor type
Research organisation

Website
http://www.skion.nl/

ROR
https://ror.org/01zs6bp63

Funder(s)

Funder type
Government

Funder Name
Dutch governmental grant (The Netherlands)

Funder Name
Dutch Health Insurance (The Netherlands)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/10/2009	20/08/2021	Yes	No