

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
Registration date 28/02/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 20/08/2021	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

Survival

Key secondary outcome(s)

Event free survival

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

1 Years

Upper age limit

18 Years

Sex

Not Specified

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)

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

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