Protocol for treatment and research of acute lymphoblastic leukaemia of childhood
of the Dutch Childhood Oncology Group (SNWLK/DCOG ALL-9).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21934

Source
Nationaal Trial Register

Brief title
SNWLK-ALL-9

Health condition

Acute lymphoblastic leukaemia of childhood.

Sponsors and support

Primary sponsor: DCOG
Source(s) of monetary or material Support: health insurance and governement

Intervention

Outcome measures

Primary outcome

Survival.

Secondary outcome

Event free survival.

Study description

Background summary

The dutch ALL-6 protocol (1984-1988) for standard risk childhood ALL was one of the first to use dexamethasone as 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. Presently the probability of 5-year EFS is 80%+/-2%, (for SR patients 83%, for HR patients 70%)overall.

Study objective

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 reststance testing;

5. Standardise the minimal residual disease test;

6. Evaluate the side effects, especially osteonecrosis and psychological effects of dexamethasone.

Study design

N/A

Intervention

Stratification into standard risk and high risk.

Contacts

Public
Stichting Kinder Oncologie (SKION),
Leyweg 299
J.G. Ridder-Sluiter, de
Den Haag 2545 CJ
The Netherlands
+31 (0)70 3674545
Scientific
Stichting Kinder Oncologie (SKION),
Leyweg 299
J.G. Ridder-Sluiter, de
Den Haag 2545 CJ
The Netherlands
+31 (0)70 3674545

Eligibility criteria

Inclusion criteria

All children with acute lymphoblastic leukaemia from 1 year (365 days) until 18 years of age, excluding mature B-cell ALL.

Exclusion criteria

1. Mature B-cell ALL;

2. Relapsed ALL;

3. Secondary ALL;

4. Pretreatment with corticostroids or cytostatic drugs in the 4 weeks preceding diagnosis;

5. Patient of whom essential diagnostic tests are missing;

6. Patients in whom essential parts of therapy were not given.

Study design

Design

Study type:	Interventional
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-1997
Enrollment:	918
Type:	Actual

Ethics review

Positive opinion

Date:	24-08-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL420

Register	ID
NTR-old	NTR460
Other	: N/A
ISRCTN	ISRCTN21542083

Study results

Summary results
N/A