Screening for transient leukemia in children with Down syndrome.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19924

Source
NTR

Brief title
N/A

Health condition

Transient myeloproliferative disorder in children with Down syndrome.

Sponsors and support

Source(s) of monetary or material Support: KIKA
Stichting Sophia

Intervention

Outcome measures

Primary outcome

1. To determine the population-based frequency of TMD;

2. To establish and investigate the relation of TMD and ML-DS;

3. To see if treatment of TMD can prevent TMD-associated mortality and the development of

ML-DS in later life.

Secondary outcome

1. To detect new genetic factors related to the progression of TMD to ML-DS;

2. To investigate the presence of lymphoid pre-leukemic clones in neonatal blood samples of TMD;

3. To describe the hematological abnormalities and clinical characteristics in patients with and without TMD.

Study description

Background summary

This is a prospective national screening study in which preferably all newborns with Down syndrome are screened for TMD.
If there is TMD, the children will be evaluated to see if there is a clinical indication for treatment.
Treatment is low-dose cytarabin.
Also, children who have high Minimal Residual Disease at week 8 will be treated.
Goal is to establish MRD-negativity (below threshold) at week 12.
All the children go into follow up to see if and when they develop ML-DS.

Study objective

Prevention of the progression of TMD to ML-DS by chemotherapeutical profylaxis can be possible.

Study design

1. Time point 1: < week 4;

2. Time point 2: at week 8;

3. Time point 2A: at week 10, only for those who were treated because of high MRD-levels at week 8;

4. Time point 3: at week 12.

Intervention

Treatment will be advised when there is high MRD (above threshold) at week 8.

Contacts

Public
Dept of Paediatric Haematology/Oncology
Erasmus MC- Sophia Children's Hospital
POB 2060
M. Blink
Rotterdam 3000 CB
The Netherlands
+31 (0)10 7044640
Scientific
Dept of Paediatric Haematology/Oncology
Erasmus MC- Sophia Children's Hospital
POB 2060
M. Blink
Rotterdam 3000 CB
The Netherlands
+31 (0)10 7044640

Eligibility criteria

Inclusion criteria

1. All children with Down syndrome;

2. Age < 4 weeks;

3. If blasts are present in pleural or pericardial effusion, or in a liverbiopsy (in absence of blasts in peripheral blood);

4. Signed informed consent.

Exclusion criteria

1. Children in whom the diagnosis Down syndrome can not be confirmed;

2. Complications that make sampling unwanted or impossible.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2008
Enrollment:	811
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-02-2009
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	NL1587
NTR-old	NTR1667
Other	METC ErasmusMC : 2007-168
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

Blink M, Buitenkamp TD, van Wouwe JP, van Wering ER, van der Velden VHJ, Zwaan CM. Ontwikkelingen in de diagnostiek en behandeling van leukemie bij kinderen met Down syndroom. Tijdschrift voor Kindergeneeskunde. Accepted for publication.