

Myeloid Leukaemia Down Syndrome 2006 for the treatment of myeloid leukaemia in children with Down syndrome

Submission date 17/02/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/03/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/03/2009	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Myeloid Leukaemia Down Syndrome 2006 for the treatment of myeloid leukaemia in children with Down syndrome: a multicentre, open-label, non-randomised trial with direct individual benefit

Acronym
ML-DS 2006

Study objectives

1. Standardisation of treatment for all children with Down syndrome (DS) and myeloid leukaemia (ML)
2. Achievement of an overall survival of 85% in all participating institutions
3. Optimisation of the quality of supportive therapy
4. Establishment of an international network of coordinated research in ML and DS

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ethics committee of the University of Münster gave approval on 29th March 2007 (ref: 3VCreutzig 10)
2. Ethics committee of the Hannover Medical School gave approval on the 24th May 2007 (ref: 4378M)

Study design

Multi-centre open-label non-randomised trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Myeloid leukaemia of down syndrome

Interventions

Four elements of polychemotherapy:

Course 1:

Cytarabine 100 mg/m²/day on days 1 and 2
Cytarabine 100 mg/m²/12 hours on days 3 - 8
Idarubicin 8 mg/m²/day on days 3, 5 and 7
Etoposide 150 mg/m²/day on days 6, 7 and 8
Cytarabine intrathecal (i.th.) on day 1

Course 2:

Cytarabine 500 mg/m²/day on days 1 - 4
Idarubicin 5 mg/m²/day on days 3 and 5
Cytarabine intrathecal (i.th.) on day 1

Course 3:

High dose (HD) cytarabine 1 g/m²/12 hours on days 1 - 3
Mitoxantrone 7 mg/m²/day on days 3 and 4
Cytarabine intrathecal (i.th.) on day 1

Course 4:

High dose (HD) cytarabine 3 g/m²/12 hours on days 1 - 3
Cytarabine intrathecal (i.th.) on day 1

In children with a body weight less than or equal to 12 kg, the dosages are calculated according to body weight. After each course, a lumbar puncture and one marrow aspiration is performed at the following points:

Course 1: day one

Course 2: day 28

Course 3: days 42 - 56

Course 4: approximately day 88

The following information is collected:

1. Online documentation of treatment elements
2. Toxicity
3. Minimal residual disease

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Event free survival
2. Overall survival

Measured at days 1, 28, 42 - 56 and 88.

Key secondary outcome(s)

Reduction of toxicity, measured at days 1, 28, 42 - 56 and 88.

Completion date

31/12/2012

Eligibility

Key inclusion criteria

1. Children with trisomy 21/trisomy 21 mosaic and myeloid leukaemia
2. Aged greater than 6 months to 4 years of age with/without GATA1 mutation, or aged greater than 4 years of age to 18 years of age with GATA1 mutation, either sex
3. Patients, in the above age group, must have DS and ML
4. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 months

Upper age limit

4 years

Sex

All

Key exclusion criteria

1. Children without DS
2. Children with DS and transient myeloproliferative disorder (TMD)
3. Children with DS and acute lymphoblastic leukaemia (ALL)
4. Accompanying diseases which do not allow therapy according to the protocol
5. Pre-treatment greater than 14 days with intensive induction therapy

Date of first enrolment

01/01/2007

Date of final enrolment

31/12/2012

Locations

Countries of recruitment

Czech Republic

Denmark

France

Germany

Netherlands

Norway

Slovakia

Sweden

Study participating centre

Carl-Neuberg-Str. 1

Hannover

Germany

30625

Sponsor information

Organisation

University of Münster (Germany)

ROR

<https://ror.org/00pd74e08>

Funder(s)**Funder type**

Charity

Funder Name

German Cancer Aid (Deutsche Krebshilfe) (Germany)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration