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

Submission date	Recruitment status	Prospectively regi
17/02/2009	No longer recruiting	[_] Protocol
Registration date	Overall study status	[] Statistical analysis
19/03/2009	Completed	[_] Results
Last Edited	Condition category	Individual particip
19/03/2009	Cancer	[] Record updated ir

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

istered

is plan

- pant data
- in last year

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

Secondary study design Non randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Myeloid leukaemia of down syndrome

Interventions

Four elements of polychemotherapy:

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

Course 2: Cytarabine 500 mg/m^2/day on days 1 - 4 Idarubicin 5 mg/m^2/day on days 3 and 5 Cytarabine intrathecal (i.th.) on day 1

Course 3: High dose (HD) cytarabine 1 g/m^2/12 hours on days 1 - 3 Mitoxantrone 7 mg/m^2/day on days 3 and 4 Cytarabine intrathecal (i.th.) on day 1

Course 4: High dose (HD) cytarabine 3 g/m^2/12 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 measure

Event free survival
Overall survival

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

Secondary outcome measures

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

Overall study start date 01/01/2007

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

Age group Child

Lower age limit 6 Months

Upper age limit

4 Years

Sex

Both

Target number of participants 150

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)

Sponsor details Domagkstr. 5 Münster Germany 48149 ukm@uni-muenster.de

Sponsor type University/education

Website http://www.klinikum.uni-muenster.de

ROR https://ror.org/00pd74e08

Funder(s)

Funder type Charity

Funder Name

German Cancer Aid (Deutsche Krebshilfe) (Germany)

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