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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	[_] Prospectively registered [_] Protocol
Registration date 19/03/2009	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 19/03/2009	**Condition category** Cancer	[_] Individual participant data [_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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
1. Event free survival
2. 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
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Sponsor information

Organisation
University of Münster (Germany)

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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