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Prevention of myeloid leukaemias in children with Down's syndrome and Transient Myeloproliferative Disorder

Submission date	Recruitment status	[ ] Prospectively registered
30/05/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/07/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/02/2009	Cancer	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
https://aml.mh-hannover.de/dsml/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TMD Prevention 2007

Study information

Scientific Title

Acronym
TMD Prevention 2007

Study objectives
Elimination of the preleukaemic clone in children with Down's syndrome and Transient Myeloproliferative Disorder (TMD) to prevent Acute Myeloid Leukaemia (AML).

As of 17/02/2009 this record was updated to include the following countries of recruitment: Netherlands, Czech Republic, Slovakia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Ethical Committee of the Hannover Medical School on the 17th November 2006 (ref: 4378M).

Study design
Non-randomised, historically controlled trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Transient myeloproliferative disorder in children with Down's syndrome

Interventions
Experimental intervention:
Monitoring of GATA1s positive preleukemic clones, low-dose cytarabine treatment in children with persisting GATA1s clone.

Control intervention:
None, historical controls are used.

Duration of intervention per patient: three months

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Cytarabine

Primary outcome measure
Reduction of Down's Syndrome Myeloid Leukaemia (DS-ML) risk in children with TMD from 22% to 7%.

Secondary outcome measures
1. Key secondary endpoint: GATA1s negativity (sensitivity 10-3/-4) at week 12
2. Assessment of safety: Serious Adverse Events (SAE)/Suspected Unexpected Serious Adverse Reaction (SUSAR) reporting system, long-term follow-up of late adverse effects, data monitoring committee

Overall study start date
01/05/2007

Completion date
30/04/2012

Eligibility

Key inclusion criteria
TMD with GATA1s mutation and myeloproliferation (greater than 5% blasts in peripheral blood or bone marrow).

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
100

Key exclusion criteria

1. No consent
2. No trisomy 21

Date of first enrolment
01/05/2007

Date of final enrolment
30/04/2012

Locations

Countries of recruitment
Czech Republic

Germany

Netherlands

Slovakia

Study participating centre
Pediatric Hematology/Oncology
Hannover
Germany
30625

Sponsor information

Organisation
Hannover Medical School (Germany)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.mh-hannover.de/

ROR

https://ror.org/00f2yqf98

Funder(s)

Funder type
Research organisation

Funder Name
German Research Foundation (Deutsche Forschungsgemeinschaft [DFG]) (Germany) - (ref: RE 2580/1-1)

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