

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

Submission date 30/05/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/07/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/02/2009	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

Study website

<https://aml.mh-hannover.de/dsml/>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Carl-Neuberg-Str. 1

Hannover

Germany

30625

reinhardt.dirk@mh-hannover.de

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