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Influence of anthroposophical supportive medicine on treatment-related toxicity in children receiving cancer therapy

Submission date 31/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/06/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 01/06/2009	**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

Study information

Scientific Title

Study objectives
Anthroposophic supportive medicine can reduce the incidence and the cause of treatment-related toxicity in children receiving cancer therapy.

As of 01/06/2009 this record was updated to include an extension to the anticipated end date of this trial; the initial end date was 31/03/2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The trial was accepted by the Local Ethics Committee of Charite University Medicine, Berlin on18 /08/2005

Study design
Randomised, controlled, phase IV trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Solid tumours, lymphoma and leukaemia

Interventions
We plan to include 340 children with malignancies to be randomly allocated to an arm with anthroposophically-supported medicine in addition to standard treatment compared to an arm with standard treatment alone.

The anthroposophical therapy, which includes mistletoe, will be partly given preventively in parallel to chemotherapy, and partly as an exactly defined intervention stand-by medication.

Intervention Type

Other

Phase
Phase IV

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Quality of life questionnaires

Overall study start date
01/11/2005

Completion date
31/03/2012

Eligibility

Key inclusion criteria
The trial will be open to patients being treated according to current protocols for solid tumours, lymphoma and leukaemia in the German Society for Paediatric Oncology and Haematology (GPOH), aged between 1 and 18 years

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
340

Key exclusion criteria
Current use of any experimental therapy

Date of first enrolment
01/11/2005

Date of final enrolment
31/03/2012

Locations

Countries of recruitment
Germany

Study participating centre
Charité - University Medicine Berlin
Berlin
Germany
13353

Sponsor information

Organisation
Helixor Heilmittel GmbH and Co. (Germany)

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Helixor Heilmittel GmbH and Co. KG
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Sponsor type
Industry

Website
http://www.helixor.de

ROR
https://ror.org/02thwp314

Funder(s)

Funder type
Industry

Funder Name
Helixor Heilmittel GmbH (Germany)

Funder Name
Weleda AG (Germany)

Funder Name
WALA Heilmittel GmbH (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