

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

Submission date 31/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/06/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/06/2009	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

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 on 18/08/2005

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)

Sponsor details

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