ISRCTN23173889 https://doi.org/10.1186/ISRCTN23173889

Molecular determinants of bone mineral density (BMD) in children with acute lymphoblastic leukemia (ALL) and the role of intervention by physical activities and calcium and vitamin D supplements as a preventive strategy

Submission date 27/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 27/01/2006	**Overall study status** Completed	
Last Edited 14/08/2009	**Condition category** Cancer	

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
NTR477; MEC number 193.291/2000/144 and 114.720/1991/62

Study information

Scientific Title

Study objectives
Intervention with adequate calcium and vitamin D and physical activities will influence BMD and fracture rate in a positive way during and after treatment for childhood ALL.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Randomised single blind placebo controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute Lymphoblastic Leukemia (ALL)

Interventions
Controlled physical activities

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Increase of BMD

Secondary outcome measures
Decrease of fracture rate

Overall study start date
01/09/2001

Completion date
01/10/2004

Eligibility

Key inclusion criteria
Patients aged 4-18 with ALL

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Physical handicap
2. Age <3 years

Date of first enrolment
01/09/2001

Date of final enrolment
01/10/2004

Locations

Countries of recruitment

Netherlands

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
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Sponsor information

Organisation
Erasmus Medical Center, Sophia Children's Oncology Center Rotterdam (KOCR) (Netherlands)

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Sponsor type
Not defined

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medical Centre, Sophia Children's Oncology Centre, Rotterdam (KOCR)

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