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

Plain English summary of protocol

Not provided at time of registration

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

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

Study participating centre Erasmus Medical Center Rotterdam Netherlands

3000 CB

Sponsor information

Organisation

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

Sponsor details

P.O. Box 2060 Rotterdam Netherlands 3000 CB +31 (0)10 4636691 j.dito@erasmusmc.nl

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 summaryNot provided at time of registration