

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
Registration date 27/01/2006	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 14/08/2009	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

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised single blind placebo controlled parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute Lymphoblastic Leukemia (ALL)

Interventions

Controlled physical activities

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Increase of BMD

Key secondary outcome(s)

Decrease of fracture rate

Completion date

01/10/2004

Eligibility

Key inclusion criteria

Patients aged 4-18 with ALL

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

4 Years

Upper age limit

18 Years

Sex

All

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

3000 CB

Sponsor information

Organisation

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration