# 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	<ul><li>Record updated in last year</li></ul>

# 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

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

#### Study design

Randomised single blind placebo controlled parallel group trial

#### Primary study design

Interventional

#### 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