

Study Into the Effect of Pamidronate for the Prevention of Heterotopic Ossification in High-Risk Patients: A Randomized Controlled Trial

Submission date 26/01/2006	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/03/2006	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 01/02/2019	Condition category Musculoskeletal Diseases	<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
NCT00262392

Secondary identifying numbers
N/A

Study information

Scientific Title

Study Into the Effect of Pamidronate for the Prevention of Heterotopic Ossification in High-Risk Patients: A Randomized Controlled Trial

Study objectives

The purpose of this study is to determine whether bisphosphonates in comparison to radiation therapy are effective in the prophylaxis and treatment of Heterotopic Ossification (HO) in high-risk patients

Ethics approval required

Old ethics approval format

Ethics approval(s)

The trial was approved by the Ethics Committee of Basel (EKBB), reference number: 129/05

Study design

Prospective, active-controlled, intervention trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Established heterotopic ossification

Interventions

Pamidronate (Aredia) versus radiation therapy

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Pamidronate

Primary outcome measure

Primary endpoint is the radiological HO recurrence rate

Secondary outcome measures

Secondary endpoints are the clinical, functional and biochemical outcome (as assessed by several clinical and laboratory markers)

Overall study start date

01/06/2005

Completion date

01/06/2008

Eligibility**Key inclusion criteria**

Consecutive patients with established HO (Brooker grade III-IV), hospitalized for resection of HO lesions

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

40

Key exclusion criteria

1. Age <20 years
2. Vitamin D deficiency (25OH vitamin D <30 ng/ml)
3. Renal insufficiency (clearance <50 ml/min)
4. Intolerance of bisphosphonates
5. Unable to provide informed consent

Date of first enrolment

01/06/2005

Date of final enrolment

01/06/2008

Locations**Countries of recruitment**

Switzerland

Study participating centre
Petersgraben 4
Basel
Switzerland
4031

Sponsor information

Organisation
University Hospital of Basel (Switzerland)

Sponsor details
Departement of Internal Medicine
Petersgraben 4
Basel
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4031
-
Muellerb@uhbs.ch

Sponsor type
University/education

ROR
<https://ror.org/04k51q396>

Funder(s)

Funder type
University/education

Funder Name
University Hospital Basel, Switzerland

Funder Name
Freie Medizinische Gesellschaft (FAG)

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