

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

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

**ClinicalTrials.gov (NCT)**  
NCT00262392

## 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

**Study type(s)**

Treatment

**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(s)**

Primary endpoint is the radiological HO recurrence rate

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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)

**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

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration