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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

Registration date
06/03/2006

Overall study status
Stopped

Last Edited
01/02/2019

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Philipp Schuetz

Contact details
Petersgraben 4
Basel
Switzerland
4031
-
Schuetzp@uhbs.ch

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00262392

Protocol serial number
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

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