ISRCTN01332857 https://doi.org/10.1186/ISRCTN01332857

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

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
Switzerland
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