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Treatment of benign bone lesions with an injectable bone filler material

Submission date
14/07/2022

Recruitment status
No longer recruiting

Registration date
21/07/2022

Overall study status
Completed

Last Edited
21/07/2022

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Background and study aims
Benign bone lesions are areas of bone that are changed or damaged but are not cancerous. The established surgical treatments of benign bone lesions consist of open and minimally invasive surgery. In recent years, injectable and moldable bone graft materials have been developed for filling fluid-filled bone lesions in minimally invasive surgery. This study aims to retrospectively assess minimally invasive and open surgeries using an injectable bone graft material.

Who can participate?
Patients treated with an injectable bone graft material for benign bone lesions with a complete set of data and a postoperative follow-up of at least 1 year

What does the study involve?
The clinical records and x-ray images of patients are assessed.

What are the possible benefits and risks of participating?
Although there are no direct benefits for reviewed patients, future patients and treating surgeons might benefit from the conclusions made from this retrospective data analysis.

Where is the study run from?
Medical University of Vienna (Austria)

When is the study starting and how long is it expected to run for?
February 2016 to March 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Catharina Chiari, catharina.chiari@meduniwien.ac.at

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1218/2016

Study information

Scientific Title
Treatment of benign bone lesions with an injectable biphasic bone substitute

Study objectives
Injectable biphasic bone graft substitutes represent a modern alternative for conventional options of bone defect filling, as they further open the possibilities of percutaneous cavity reconstruction. Although recent studies showed good surgical outcomes after treatment with injectable biphasic bone graft substitutes, mid-term follow-ups are still missing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/07/2016, Ethics Committee of the Medical University of Vienna (Borschkegasse 8b /E06, Vienna, Austria; +43 (0)1 40400 21470; ethik-kom@meduniwien.ac.at), ref: 1218/2016

Study design
Retrospective single-center data analysis

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Benign bone lesions

Interventions
After the approval of the local ethics committee, a retrospective data analysis of the in-house software system will identify patients who were treated with Cerament® Bone Void Filler (Bonesupport™, Lund, Sweden) for benign bone lesions. After the application of inclusion criteria, patients will be included in this retrospective analysis.

Research questions:
1. What was the treatment failure rate after surgical treatment with a biphasic ceramic bone substitute?
2. How did the cavity morphology change in the postoperative course?
3. What were the treatment-specific complications?

Intervention Type
Procedure/Surgery

Primary outcome measure
Local recurrences identified by retrospective analysis of patient charts in the timeframe between surgery and last follow-up at the outpatient clinic

Secondary outcome measures
1. Postoperative cavity morphology changes assessed using x-rays at 6 weeks, 3 months, 6 months, 12 months, 18 months and at the last follow-up after surgery (MRI will be assessed in cases of suspected recurrence or incomplete cavity consolidation)
3. Postoperative complications assessed by review of patient charts in the timeframe between surgery and last follow-up at the outpatient clinic

Overall study start date
17/02/2016

Completion date
27/03/2022

Eligibility

Key inclusion criteria
Patients who:
1. Received treatment with a ceramic biphasic bone substitute
2. For benign bone tumors and tumor-like lesions
3. With a complete set of retrospective information, including surgical protocols, X-rays, patient dismission letters and outpatient clinic protocols
4. With a minimum follow-up of 1 year after surgery

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
18

Total final enrolment
18

Key exclusion criteria
1. Inconclusive data with missing surgical or histological reports

Date of first enrolment
27/07/2016

Date of final enrolment
18/12/2021

Locations

Countries of recruitment
Austria

Study participating centre
Medical University of Vienna
Währinger Gürtel 18-20
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Sponsor information

Organisation
Medical University of Vienna

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Sponsor type
University/education

Website
http://www.meduniwien.ac.at/homepage/1/homepage/

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Submitted manuscript to a peer-reviewed journal

Intention to publish date
27/03/2023

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study are available upon reasonable request from Ao.Univ.-Prof. Dr Catharina Chiari (catharina.chiari@meduniwien.ac.at). Type of

data: retrospective data including demographic parameters, surgery-specific data, data on preoperative and postoperative imaging. The pseudonymized data will become available on reasonable request after study publication for members of the scientific community.

IPD sharing plan summary

Available on request