

Treatment of benign bone lesions with an injectable bone filler material

Submission date 14/07/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/07/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 21/07/2022	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact name

Prof Catharina Chiari

Contact details

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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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 dismissal letters and outpatient clinic protocols
4. With a minimum follow-up of 1 year after surgery

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

All

Sex

All

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

Vienna

Austria

1090

Sponsor information

Organisation

Medical University of Vienna

ROR

<https://ror.org/05n3x4p02>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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