# Carbon fibre reinforced PEEK versus conventional prophylactic internal fixation in patients with low grade chondrosarcoma

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Objective is to compare field inhomogeinity between conventional titanium osteosynthesis and CFR-PEEK osteosynthesis on MR imaging. Visualisation of regions of interest will be scored and volume of field inhomogeneity will be calculated.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue neoplasms
Study type	Interventional

# Summary

# ID

NL-OMON45703

**Source** ToetsingOnline

**Brief title** CFR-PEEK

# Condition

• Musculoskeletal and connective tissue neoplasms

#### Synonym

Chondrosarcoma/ low grade bone tumour

#### **Research involving**

Human

### **Sponsors and support**

#### Primary sponsor: Leids Universitair Medisch Centrum

1 - Carbon fibre reinforced PEEK versus conventional prophylactic internal fixation ... 24-05-2025

#### Source(s) of monetary or material Support: Afdeling orhtopedie/LUMC

#### Intervention

Keyword: Carbon, CFR-PEEK, Chondrosarcoma, Osteosynthesis

#### **Outcome measures**

#### **Primary outcome**

Primary study parameter is the influence of field inhomogeneity on visualisation of anatomical structures of importance. A scoring system similar to the scoring systems of Zimel will be used (see attached publication). Excochleation borders on MRI will be scored using a 5 point scoring system. Visualisation will be graded with percentage of the excochleation borders visual on MRI as follows: 1=0-20%, 2=20-40%, 3=40-60%, 4=60-80%, 5=80-100%. A subjective scoring system is composed to reflect the degree of certainty that recurrence of tumour is absent to the observer (musculoskeletal radiologist/ oncologic orthopaedic surgeon). Grading will be as follows: 1= completely uncertain, 2=uncertain, 3=some degree of certainty, 4=certain, 5= definite. Sequences used to score the MR images are; T1, T2, T1 gadolinium and T2 fat suppression. All sagittal and transversal coupes will be used for evaluation. In addition total field inhomogeneity volume will be calculated.

#### Secondary outcome

# **Study description**

#### **Background summary**

Chondrosarcoma accounts for 25% of the primairy bone sarcomas. The clinical behaviour of these tumours is highly variable and unpredictable. Grade 2 and 3 are considered highly aggressive and invasive sarcomas, while Grade 1 is often considered to be slowly growing and not prone to metastasize.

The 5-year survival rates reported for low-grade chodrosarcomas are 85%-90% in contrast to 20-40% reported survival rates for high grade tumours. Because of the relative ineffectiveness of chemo- and radiotherapy, surgical excision is the treatment of choice3.

For grade 2 and 3 chondrosarcomas, wide excision is universally accepted as standard care. For grade 1 chondorsarcomas, treatment is subject of debate.

Local treatment with intralesional curettage and an adjuvant therapy showed equivalent results to en bloc resection with respect to survival, recurrence and metastasizing potential11. En bloc resection and subsequent reconstruction with endoprostheses, bonegrafting or combinations of the before mentioned puts patients at risk for complications such as infection, aseptic loosening, periprosthetic fracturing and nonunion.

Local treatment is composed of intralesional curettage with phenolisation or cryotherapy as adjuvant therapy. After curettage and adjuvant therapy, the defect is filled with auto- or allogenic bone grafts with or without PMMA. Stability of the construct is assessed and decision is made if internal fixation is needed to prevent secondary pathologic fractures.

Recurrence rates after curettage and adjuvant therapy are 0-13.3%. Therefore accurate radiographic surveillance is of the upmost importance. Metallic implants impede reliable follow up by creating field inhomogeneity and scatter artifacts on MRI and CT and by interference on x-ray18. Despite of the fact that secondary pathologic fracture rates are 10 up to 17% in literature some studies advocate that internal fixation should be avoided because of aforementioned scatter and interference5. If field inhomogeneity and scatter on imaging would no longer be an issue internal fixation could be indicated more often and could reduce secondary pathologic fracture risk.

Because of the potential imaging advantages at follow up and the subsequent potential to reduce secondary pathologic fractures in ACT/chondrosarcoma grade 1 cases, we will perform a prospective cohort study to test radiographic properties of CFR-PEEK distal femoral plate osteosynthesis. Data will be compared to a retrospective cohort with conventional titanium distal femoral plate osteosynthesis. Visualisation of the excochleation borders and cortical window will be scored. Volumes of field inhomogeneity and scatter artifacts will be measured and ingrowth of the cortical window will be assessed.

#### **Study objective**

Objective is to compare field inhomogeinity between conventional titanium osteosynthesis and CFR-PEEK osteosynthesis on MR imaging. Visualisation of regions of interest will be scored and volume of field inhomogeneity will be calculated.

#### Study design

This is a prospective cohort study to evaluate radiographic properties of the CFR-PEEK distal femoral internal fixation plates. Field inhomogeneity on MR imaging in patients that underwent curettage and adjuvant therapy for an ACT/grade 1 chondrosarcoma will be analysed. Follow-up will be one year. In addition, a retrospective study will be performed to compare results with the prospectively collected results of the CFR-PEEK distal femoral internal fixation plates. Data will be collected prospectively according to the standard follow up protocol.

#### Intervention

Distal femoral prophylactic plate osteosynthesis with a Carbon Fibre Reinforced PolyEtherEtherKetone distal femoral plate (CFR-PEEK, Carbofix).

#### Study burden and risks

Potential benefit of enrollment in this study is superior radiographic surveillance due to the absence of field inhomogeneity and scatter artifacts caused by titanium implants. Recurrences could be detected in an earlier stage which may have a positive effect on limb salvage and oncologic outcome. Furthermore the field inhomogeneity and scatter artifacts in titanium implants have been causing a restraint on the use of prophylactic osteosynthesis. Using CFR-PEEK implants could widen indication of prophylactic use of osteosynthesis and thus could reduce secondary fracture rates after curettage and adjuvant therapy.

Mechanical properties of the CFR-PEEK implants (i.e. higher bending strength and improved modulus of elasticity) could reduce hardware failure rates and fixation failure rates.

Potential risk of using CFR-PEEK is brittleness of the CFR-PEEK implants when hardware failure occurs. In literature, only in the early generation CFR-PEEK implants this complication was seen. Improved manufacturing processes and thicker composites and coatings resulted in diminished failure rates. Although biocompatibility is addressed in literature, one case report reported a biologic reaction to carbon particles. Therefore, tissue reactions should be considered a potential risk.

All follow-up will be part of normal patient care, no extra imaging or

questionnaires will be used outside standard care.

# Contacts

#### Public

Leids Universitair Medisch Centrum

Albinusdreef 2 Leiden 2333 ZA NL **Scientific** Leids Universitair Medisch Centrum

Albinusdreef 2 Leiden 2333 ZA NL

# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

- 1) Males and females, 18 years of age or older
- 2) Primary treatment of an ACT/chondrosarcoma grade 1 with curettage
- 3) Adjuvant treatment with phenolysation or cryotherapy
- 4) Indication for prophylactic osteosynthesis

### **Exclusion criteria**

- 1) Primary pathologic fracture
- 2) Re-excision of an ACT/chondrosarcoma grade 1
- 3) Defect reaching into knee joint
- 4) Treatment with knee arthroplasty
- 5) Likely problems, in the judgement of the investigator, with maintaining follow up

# Study design

### Design

Study type: Interventional	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

### Recruitment

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NL	
Recruitment status:	Recruiting
Start date (anticipated):	30-08-2017
Enrollment:	52
Туре:	Actual

### Medical products/devices used

Generic name:	Piccolo Composite Plate
Registration:	Yes - CE intended use

# **Ethics review**

Approved WMO	
Date:	03-05-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

#### Approved WMO

6 - Carbon fibre reinforced PEEK versus conventional prophylactic internal fixation ... 24-05-2025

Date: Application type: Review commission: 27-11-2017 Amendment METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

# **Study registrations**

# Followed up by the following (possibly more current) registration

No registrations found.

# Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register CCMO ID NL60638.058.17