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Minimal invasive treatment of cartilage forming bone cancer

Submission date 06/01/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/01/2017	**Overall study status** Completed	
Last Edited 18/07/2017	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Atypical cartilaginous tumours (ACT) are cartilage-producing tumours that arise from the bone. They have an intermediate malignant potential, which means that the tumours do not spread (metastasise) and patients do not usually die. However, they are treated often since they have a unknown potential to transform to more malignant tumours and spread, or they have local negative effects such as weakening of the bone. Treatment is still a topic of debate, since up to two decades ago whole segments of bone were removed (en bloc resection) and nowadays some physicians suggest to only monitor these tumours. Nevertheless, research in the last decade has shown that only removal of the tumour itself and not the surrounding bone (intralesional surgery) is successful in terms of tumour eradication and patient survival. However, this treatment can still lead to burdens such as hospital admission, long rehabilitation and complications. Therefore, the aim of this study is to investigate the effect of minimal invasive treatment of these tumours by radiofrequency ablation (RFA). In RFA, a needle is used that heats the tumour leading to cell death of the tumour (ablation).

Who can participate?
Patients aged 18 and over with an ACT in the long bones that needs surgery

What does the study involve?
Participants first undergo a biopsy (to take a sample of the tumour) and RFA in the same procedure under local or general anaesthetic. Three months later, a MRI scan is taken of the bone to assess the effect of the tumour ablation. Shortly after the MRI scan, patients receive the standard care of intralesional surgery. The material retrieved during surgery is sent to the pathologist to see if the tumour has been killed sufficiently by the previous RFA procedure.

What are the possible benefits and risks of participating?
The potential benefits of RFA are that it can be done through a small incision (cut) in the skin, and after the procedure full weight-bearing on the affected leg is often possible. The number of complications is lower compared to more invasive surgery, although burning wounds and fractures have been reported occasionally.

Where is the study run from?
The Departments of Orthopaedic Surgery, Radiology and Pathology of the University Medical Center Groningen, University of Groningen (Netherlands)

When is the study starting and how long is it expected to run for?
January 2009 to December 2013

Who is funding the study?
University Medical Center Groningen (Netherlands)

Who is the main contact?
Edwin F. Dierselhuis
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
M09.077334

Study information

Scientific Title
Radiofrequency ablation: an alternative to curettage in the treatment of atypical cartilaginous tumours in the long bones

Study objectives
The aim of this study is to report on progressing experience with radiofrequency ablation (RFA) as a treatment for atypical cartilaginous tumours (ACT) in the long bones.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee - University Medical Center Groningen - University of Groningen, 18/09/2009,
ref: M09.077334

Study design
A prospectively kept dataset of patients treated with RFA for ACT in the long bones is analysed. A CT-guided biopsy followed by RFA in the same session is conducted. Three months later, gadolinium-enhanced magnetic resonance imaging (Gd-MRI) will be performed to assess tumour ablation, followed within four weeks by curettage and adjuvant phenolization.

Primary study design
Interventional

Secondary study design
Non randomised study

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
Atypical cartilaginous tumors (ACT) in the long bones

Interventions
Patients are first percutaneously treated by radiofrequency ablation (RFA) (intervention), and subsequently treated by standard care (curettage) (control). As a result, they serve as their own control.

Patients undergo a CT-guided biopsy followed by RFA under locoregional or general anaesthesia in the same session. Three months later, gadolinium-enhanced magnetic resonance imaging (Gd-MRI) is performed to assess tumour ablation, followed within 4 weeks by curettage and adjuvant phenolization. The material retrieved during this procedure is sent to the pathologist to see if the tumour has been killed sufficiently by the previous RFA procedure.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Percentage of patients who had a complete tumour ablation on a histological level
2. Percentage of tissue necrosis on a histological level
Both measured by analysing removed tissue in the Pathology department at a single timepoint directly after surgery

Secondary outcome measures
1. Signs of residual tumour, measured using Gd-MRI at 3 months after RFA
2. Occurrence of complications, which were not recorded on specific timepoints
3. Disease-free survival after curettage, measured using at Gd-MRI at 6 months, 12 months and 24 months.
4. Functional outcome, assessed by musculoskeletal tumour society (MSTS) scores at 6 and 12 weeks after RFA and 6 and 12 weeks and 1 year after standard care

Overall study start date
01/01/2009

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Age 18 years and above
2. Clinical suspicion of ACT in the long bones that needs surgical intervention

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Tumour size > 50 mm
2. Tumour localised in the hand, foot, pelvis or axial skeleton
3. Presence of cognitive impairments
4. Previous treatment of the same lesion

Date of first enrolment
18/09/2009

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen - University of Groningen
Netherlands
9700 RB

Sponsor information

Organisation
Universitair Medisch Centrum Groningen

Sponsor details
Hanzeplein 1
Groningen
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9700 RB

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitair Medisch Centrum Groningen

Alternative Name(s)
University Medical Center Groningen, UMCG

Funding Body Type

Government organisation

Funding Body Subtype
Local government

Location
Netherlands

Results and Publications

Publication and dissemination plan
The first results have been published (see Publication Summary field). Future plans are to publish the remaining results and follow-up in high-impact peer-reviewed journals.

Intention to publish date
01/11/2014

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mr Edwin Dierselhuis (e.f.dierselhuis@umcg.nl).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2014		Yes	No