ISRCTN63060594 https://doi.org/10.1186/ISRCTN63060594

Allograft reconstruction of the extensor mechanism after resection of soft tissue sarcoma

Submission date
27/11/2017

Recruitment status
No longer recruiting

Registration date
04/12/2017

Overall study status
Completed

Last Edited
29/06/2018

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Soft tissue sarcomas are a group of rare cancers that impact the tissues, connect and support the body and organs. As they are rare and can vary in types, they are hard to diagnose. The knee joint and surrounding area are quite uncommon locations for soft tissue sarcoma. Over the recent decades, limb-sparing surgery has become an accepted method of treatment for most patients with soft tissue sarcomas. Advances in surgical techniques, prosthetic design and bone allograft banking have opened the avenue for reconstruction procedures after wide excision of bone and soft tissues. This allows the surgeon to achieve adequate margins while salvaging the limb and its function. Yet, soft tissue tumors around the knee joint still pose problems for the excision and subsequent reconstruction. Extension of the tumor in the joint or in the extensor mechanism is a challenging situation to achieve adequate margins and a good functional limb. There is no current consensus as to the best method of reconstruction of the extensor mechanism of the knee. Few reconstructive options are available to avoid knee arthrodesis including tendon transfers or local grafts, synthetic materials and allograft tissues. Regardless of the used reconstruction technique, the principal technical difficulty remains restoration of the extensor function and the provision of soft tissue coverage. In the current literature, no data is available considering specifically the demanding situation of soft tissue sarcomas involving the extensor mechanism of the knee. This study aims to highlight the surgical difficulties as well as the oncological and functional results after a resection of the extensor apparatus due to a soft tissue sarcoma.

Who can participate?
Adults aged 34 to 68 years old who underwent surgical resection of their soft tissue sarcoma using the extensor method.

What does the study involve?
Participants who underwent a resection of a soft tissue sarcoma involving the extensor mechanism are contacted and asked to participate in further follow up. Participants are provided with questionnaires to fill out about their knee function. Participants are also follow up with serial clinical and radiographic (x-rays and imaging) of their knee monthly for the first three

months of follow up and then periodically for ten years after surgery. This is done to assess the function and if there are any surgical complications of the knee.

What are the possible benefits and risks of participating?
There are no direct benefits or risks for patients taking part in the study. The treatment and surgical indication was identical between patients participating in the study and patients not participating in the study.

Where is the study run from?
1. University Hospital Careggi (Italy)
2. Balgrist University Hospital (Switzerland)

When is the study starting and how long is it expected to run for?
July 2014 to December 2016

Who is funding the study?
Balgrist University Hospital (Swtizerland)

Who is the main contact?
Dr Daniel Müller (Scientific)
daniel.mueller@balgrist.ch

Contact information

Type(s)
Scientific

Contact name
Dr Daniel Müller

Contact details
Balgrist University Hospital
Forchstrasse 340
Zürich
Switzerland
8008

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
W-676

Study information

Scientific Title
Allograft reconstruction of the extensor mechanism after resection of soft tissue sarcoma: a case series

Study objectives
Soft tissue tumors around the knee joint still pose problems for the excision and subsequent reconstruction. The replacement of the extensor mechanism by an allograft is a reasonable option, allowing wide margins and restoration of active extension in most patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Commitee Zurich Switzerland, 10/24/2017, ref: 2017-01666

Study design
Observational case series

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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Soft tissue tumors around the knee joint

Interventions
The database is retrospectively searched for patients who underwent a resection of a soft tissue sarcoma involving the extensor mechanism. From these patients informed consent is obtained. In addition to participants regular follow ups, participants are provided with questionnaires to fill out regarding their knee function. The minimal duration of observation was 2 years. The mean follow-up was 6 years. The frequency of the controls did not vary compared to patients not included in the study.

Participants are followed with serial clinical and radiographic examinations of the limb, combined with CT imaging of the chest. For the first 3 months, clinical and radiographic follow-ups were obtained monthly. Afterwards the intervals were extended to 3 months in the first two years, four months in the 3rd year, 6 months in the 4th, 5th and 6th years and finally once a year until the 10th year after the surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Knee function the active range of motion, active flexion and extension lag is measured using the International Society of Limb Salvage (ISOLS) score at yearly follow ups and using data from reviewing the patient charts.
2. Local recurrence rate is measured using Kaplan Meier curve for local recurrence free survival for 10 years. The presence of a local recurrence was detected by careful clinical examination and radiologic controls.
3. Surgical complication rate is measured by registering all the revision surgeries of the included patients during the observational time.

Secondary outcome measures
1. Metastatic disease survival is measured using Kaplan Meier curve for metastasis free survival for 10 years. The presence of a metastasis was detected by careful clinical examination and CT chest.
2. Overall disease specific survival is measured using Kaplan Meier curve for overall survival for 10 years.
3. Functional outcome is measured by measuring the active range of motion (°), active flexion and extension lag at the last follow up. The International Society of Limb Salvage (ISOLS) score was calculated at the last follow up.

Overall study start date
01/07/2014

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Patients who have undergone a surgical resection of a soft tissue sarcoma affecting the quadriceps tendon, the patella and / or the patellar tendon without apparent joint involvement
2. Patients ranged from 34 to 68 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
6

Key exclusion criteria

Patients with involvement of the joint space needed an extra-articular knee resection and an allograft prosthetic composite reconstruction.

Date of first enrolment
01/01/2015

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Italy

Switzerland

Study participating centre
University Hospital Careggi
Firenze
Italy
50134

Study participating centre
Balgrist University Hospital
Zürich
Switzerland
8008

Sponsor information

Organisation
Balgrist University Hospital

Sponsor details
Forchstrasse 340
Zürich
Switzerland
8008

Sponsor type
Hospital/treatment centre

Website
www.balgrist.ch

ROR
https://ror.org/02yzaka98

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Balgrist University Hospital

Results and Publications

Publication and dissemination plan
The analysis of the data is finished and a manuscript is ready for submitting in a high-impact peer reviewd journal. We intent to publish the study in the next 6 months. Please use the contact details below to request a study protocol.

Intention to publish date
04/06/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Daniel Müller, daniel.mueller@balgrist.ch.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/05/2018		Yes	No