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Retrospective study in patient with soft tissue sarcoma of trunk wall and extremities who have been treated with surgery in association or not with chemotherapy and/or radiotherapy, to point out the response to preoperative treatment and outcome

Submission date
21/12/2016

Recruitment status
No longer recruiting

Registration date
21/02/2017

Overall study status
Completed

Last Edited
10/04/2017

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Soft Tissue Sarcoma (STS) is a condition in which cancer cells form in the soft tissues of the body, such as the muscles, tendons (bands of tissue that connect muscles to bones), fat and blood vessels. STS most commonly affects tissue in the arms, legs and trunk (torso). In most cases, the first treatment used to treat STS is surgically removing the tumour. This can be done in combination with radiotherapy (using high-energy radiation beams to destroy cancer cells) or chemotherapy (anti-cancer drugs). The aim of this study is to look at the medical records of people who were diagnosed with STS and were treated surgically to see if outcomes are better for those who also had radiotherapy.

Who can participate?
Adults who have been diagnosed with STS between 2008 and 2012

What does the study involve?
Participating centres are asked to prepare a list of patients with STS who were diagnosed between 2008 and 2012. Patients would have been treated with surgery alone, surgery and radiotherapy, surgery and chemotherapy, surgery and chemo-radiation (a combination of radiotherapy and chemotherapy), or surgery and isolated limb perfusion (a type of chemotherapy injected directly into the affected limb) Information from patient charts is then collected in order to find out what treatment the participants had and whether it has been successful.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating.

Where is the study run from?
1. Istituto Oncologico Veneto (Italy)
2. The Royal Marsden NHS Foundation Trust (UK)
3. Állami Egészségügyi Központ - Magyar Honvédség Központi Kórháza (Hungary)
4. Mount Sinai Hospital (Canada)
5. HM Hospitales (Spain)
6. Klinikum der Universität München (Germany)

When is the study starting and how long is it expected to run for?
October 2016 to May 2017

Who is funding the study?
Nanobiotix (France)

Who is the main contact?
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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
N/A

Study information

Scientific Title

Multicenter retrospective observational chart review on treatment management of soft tissue sarcoma patients treated by surgery with or without perioperative treatment

Acronym
ROCR

Study objectives
The primary objective of this chart review is to investigate the prognostic significance of pathological complete response (pathCR*) to a pre-operative treatment in patients with STS of trunk and extremities on Disease Free Survival (DFS**) at three years.

*PathCR is defined as greater than or equal to 95% necrosis/fibrosis or less than or equal to 5% viable cells
**DFS is defined as time between diagnosis, and local or distant relapse of the disease or occurrence of any cancer or death

Ethics approval required
Old ethics approval format

Ethics approval(s)
This is a non interventional retrospective review of patient individual charts which does not need ethical approval. In the UK, the Ethics Committee of the Royal Marsden Foundation will review the study.

Study design
Retrospective observational cohort chart review

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Malignant soft tissue sarcoma

Interventions
Each center will be asked to prepare a list of eligible patients based on inclusion and exclusion criteria. If no database of soft tissue sarcoma (STS) patients is available, the institution data manager will be asked to prepare a list of all patients newly diagnosed between 2008 and 2012 with STS. From this list a selection of eligible patients should be performed according to inclusion and exclusion criteria.

All data are collected retrospectively. The charts are reviewed once and treatment data are collected in a eCRF. Patients must have been treated between 2008 and 2012 and followed up for 3 years, data of the treatment procedure and the follow up visits are collected at one time point.

Intervention Type
Other

Primary outcome measure
Disease free survival is measured through medical record review 3 years after disease diagnosis.

Secondary outcome measures
1. Pathological response (% of necrosis, % of fibrosis, % of viable cells) is measured through review of the pathological report of the surgical specimen at the time of surgery
2. Tumor type and subtype is assessed through pathological report review at diagnosis and the time of surgery
3. Chemotherapy treatment (drug name, drug dose, treatment duration, number of cycles) is assessed by reviewing drug prescription form at each course of chemotherapy and at the end of chemotherapy treatment
4. Radiation treatment (Dose delivered, treatment duration) is assessed by reviewing medical radiation report at the end of Radiation treatment
5. Surgical procedure (conservative surgery, amputation, R0 resection, R2 resection) is assessed by reviewing the medical surgery report at the time of surgery
6. Quality of surgery (R0 resection, R1 resection, surgical margin, tumor size) is measured by reviewing pathological reports at the date of surgery
7. New tumors (local recurrence, distant recurrence, other cancer) are assessed by reviewing medical report and radiological MRI and CT scan report on the date of surgery, 6 months after surgery, 12 months after surgery, 18 months after surgery, 24 months after surgery, 30 months after surgery, 36 months after surgery
8. Quality of life (Performans status, walking distance, presence at work) is measured by reviewing medical reports on the date of diagnosis of the tumor, date of surgery, 6 months after surgery, 12 months after surgery, 18 months after surgery, 24 months after surgery, 30 months after surgery, 36 months after surgery

Overall study start date
21/10/2016

Completion date
15/05/2017

Eligibility

Key inclusion criteria
1. Primary Soft Tissue Sarcoma (STS) of the extremities and trunk wall newly pathologically diagnosed between 2008 and 2012 with STS.
2. Age ≥ 18 years old
3. Any histology (except those specified in exclusion criteria below)
4. Any grade
5. Treated by any of these therapies for the primary tumor:
5.1. Surgery alone

5.2. Surgery + radiation therapy (pre, post or per-operative)
5.3. Surgery + chemotherapy (pre or post-operative)
5.4. Surgery + chemo-radiation (pre or post-operative)
5.5. ILP (isolated limb perfusion) and surgery +/- radiation therapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20 to 200 patients per site and 1200 in total

Key exclusion criteria
1. Patients with the following histological type: bone sarcoma, Kaposi's sarcoma, primitive neuroectodermal tumor, angiosarcoma, epithelioid hemangioendothelioma
2. Benign or intermediate histological subtypes: aggressive fibromatosis, desmoid tumor or dermatofibrosarcoma protuberans
3. Gastrointestinal stromal tumour (GIST)
4. STS localized in the intra-abdominal region and retroperitoneal region
5. Re-resection for non carcinological first resection (R1 or R2)
6. Patient with metastatic disease at diagnosis of STS
7. No pathological report available at diagnosis or at surgery
8. Less than 36 months (pilot and extended phase) of data available following diagnosis unless the patient died before
9. No possibility to have access to the data
10. Concurrent active therapy for another cancer (= patient receives active treatment for this cancer during the study period)

Date of first enrolment
13/01/2017

Date of final enrolment
30/04/2017

Locations

Countries of recruitment
Belgium

Canada

England

France

Germany

Hungary

Italy

Poland

Spain

United Kingdom

Study participating centre
Istituto Oncologico Veneto
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Study participating centre
Fondazione IRCCS Istituto Nazionale dei Tumori
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Study participating centre
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Sponsor type
Other

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ROR
https://ror.org/047ts9g27

Funder(s)

Funder type
Industry

Funder Name
Nanobiotix

Results and Publications

Publication and dissemination plan
Any publication need to be approved by the Investigator coordinator and Nanobiotix. The Sponsor recognizes the Investigators' right to utilize data derived from the chart review for teaching purposes, communication at congresses and scientific publications. Nevertheless, in order to ensure the accuracy and scientific value of the information, while preserving the independence and accountability of the Investigators, and the confidentiality of the information, only cleaned, checked and validated data will be used. To that effect, it is essential that the parties exchange and discuss, prior to any publication or communication, any draft publication or communication made by the Investigator/s. Therefore, the Investigator/s undertakes, and will ensure that any Sub-Investigators undertake, not to make any publication, communication or release pertaining to the results of the chart review, without the prior written consent of the Sponsor. The Sponsor has the right at any time to publish the results of the chart review.

Intention to publish date
01/12/2017

Individual participant data (IPD) sharing plan
The datasets collected and analysed in this study are available upon reasonable request from:
Deloitte Consulting
Clémentine Demaire
Senior consultant | Health Economics and Outcomes Research
Berkenlaan 8a, 1831 Diegem, Belgium
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IPD sharing plan summary
Available on request