Short Course Of Preoperative Radiotherapy in Head and Neck-, Trunk- and Extremity Soft Tissue Sarcomas; a randomized phase II clinical trial

Published: 21-01-2021
Last updated: 14-06-2024

to compare the short-term toxicity of the conventional schedule of 25 x 2 Gy, once daily fractionation in a five-week Overall Treatment Time (OTT) to 14 x 3 Gy, once daily fractionation in a three-week OTT, with respect to the rate of postoperative...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Connective tissue disorders (excl congenital)
Study type	Interventional

Summary

ID

NL-OMON50770

Source
ToetsingOnline

Brief title
SCOPES

Condition

- Connective tissue disorders (excl congenital)
- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
sarcoma, soft tisssue sarcoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: ontvangen giften; opgebouwd budget en;indien toegekend;KWF

Intervention

Keyword: radiotherapy, short course radiotherapy, soft tissue sarcoma

Outcome measures

Primary outcome

To investigate the short-term toxicity of 25 x 2 Gy, once daily fractionation in a five-week overall treatment time with respect to the rate of postoperative wound complications up to 30 days after surgery as compared to the wound complication rate up to 30 days after surgery preceded by 14 x 3 Gy in a three week OTT.

Secondary outcome

• to study the association between 14 x 3 Gy, once daily fractionation in a three-week overall treatment time and the local control.

• to investigate the long-term toxicity of 14 x 3 Gy, once daily fractionation in a three-week overall treatment time and to report the percentage of fibrosis, edema, joint impairment and bone fractures scored by the Common Terminology Criteria for Adverse Events, CTCAE version 5.0, at 2 years follow-up.

Exploratory endpoints

• to investigate the health-related quality of life.

• to investigate patient related outcomes (e.g. radiotherapy-related

toxicities, health care consumption).

• to investigate cost-effectiveness.

Study description

Background summary

Currently, soft tissue sarcomas (STS) are preoperatively irradiated in a conventionally fractionated regimen of 25 x 2 Gy in five weeks. Recent radiobiological investigations, however, suggest sensitivity to (modest) hypofractionation. Within this study, patients will be randomized to receive either the conventional schedule of 25 x 2 Gy or a shorter preoperative regimen of 14 x 3 Gy, in the hypothesis that both the postoperative wound complication rate until 30 days after surgery, as well as the local control probability at two years are comparable in both arms

Study objective

to compare the short-term toxicity of the conventional schedule of 25 x 2 Gy, once daily fractionation in a five-week Overall Treatment Time (OTT) to 14 x 3 Gy, once daily fractionation in a three-week OTT, with respect to the rate of postoperative wound complications up to 30 days after surgery

Study design

A prospective randomized phase II clinical study

Intervention

radiotherapy
Arm A: 25 x 2 Gy with an overall treatment time of 5 weeks
Arm B; 14 x 3 Gy with an overall treatment time of 3 weeks

Study burden and risks

The study aims to reduce the treatment burden for sarcoma patients by a reduction of the number of radiation fractions and thereby patients visits to the hospital. It is hypothesized that a reduction of treatment burden will not be associated with a wound complication rate higher than 42% and will result in a benefit with respect to quality of life for participating patients

All patients have to fill out a Health related questionnaires 9 times.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
AMSTERDAM 1066CX
NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
AMSTERDAM 1066CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Histologically confirmed newly diagnosed intermediate to high grade soft tissue sarcoma localized to thethe head and neck area, trunk or chest wall or extremities, for which the standard treatment is a combination of and radiotherapy and surgery (deep seated and/or >= 5cm in largest tumor diameter and/or an anticipated close resection margin and/or grade II/III according to the FNCLCC definition);
• Absence of regional and/or distant disease. Patients must be staged by at least a CT scan of the chest Staging may also be performed by FDG-PET scanning and or total body MRI scans. Patients with an uncertain metastatic status (e.g.

small indifferent lung nodules) and patients with a low metastatic burden not precluding the application of both preoperative radiotherapy and definitive surgery, are allowed to participate;
• WHO Performance Status <= 2;
• Able and willing to undergo preoperative radiotherapy;
• Able and willing to undergo definitive surgery;
• Able and willing to comply with regular follow-up visits;
• Able and willing to complete patient reported outcome questionnaires (health-related quality of life and cost effectiveness);
• Able and willing to undergo randomization;
• Age >= 18 years;
• Signed written informed consent

Exclusion criteria

• Prior malignancies; except another malignancy and disease-free for >= 5 years, or completely resected non-melanomatous skin carcinoma or successfully treated in situ carcinoma;
• Patients with recurrent sarcomas who underwent prior radiotherapy to the target lesion (if the primary sarcoma was managed by surgery only and no perioperative RT, patients are eligible);
• Ewing sarcoma and other PNET family tumors, rhabdomyosarcomas (both pediatric and adult), osteosarcomas;
• Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial;
• Female patients who are pregnant;
• Intention to perform an isolated limb perfusion, instead of a tumor resection;
• Neoadjuvant chemotherapy to be scheduled between end of radiotherapy and definitive surgery (neoadjuvant chemotherapy before radiotherapy is allowed);

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-06-2021
Enrollment:	168
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	21-01-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	29-06-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-09-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-10-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-06-2024
Application type:	Amendment

Review commission: METC NedMec

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	ID
ClinicalTrials.gov	NCT04425967
CCMO	NL75757.031.20