A phase III randomized study of preoperative radiotherapy plus surgery versus surgery alone for patients with retroperitoneal sarcoma (RPS)

Published: 23-11-2011
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To assess whether preoperative radiotherapy, as an adjunct to curative-intent surgery, improves the abdominal local recurrence-free survival.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Soft tissue neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON41672

Source
ToetsingOnline

Brief title
STRASS

Condition

- Soft tissue neoplasms malignant and unspecified
- Soft tissue therapeutic procedures

Synonym
retroperitoneal sarcoma, sarcoma

Research involving
Human

Sponsors and support

Primary sponsor: European Organisation for Research in Treatment of Cancer (EORTC)

Source(s) of monetary or material Support: EORTC

Intervention

Keyword: radiotherapy, retroperitoneal sarcoma, surgery

Outcome measures

Primary outcome

abdominal recurrence free survival

Secondary outcome

safety secondary endpoints:

- acute toxicity profile of preoperative radiotherapy

- perioperative complications

- late complications

efficacy secondary endpoints:

- tumor response

- time to abdominal recurrence

- metastasis-free survival

- overall survival

Study description

Background summary

Approximately 10-15% of adult soft tissue sarcomas arise in the retroperitoneum. The mean annual incidence is 2.7 cases per 10^6 persons and does not change significantly over time. The sex ratio is approximately 1, and the mean age is 55. The most frequent histological subtypes are: well-differentiated liposarcomas, dedifferentiated liposarcomas and leiomyosarcomas.
RPS are marked by a poor outcome, especially over the long term. The 5-year overall survival rate is 50-60%, significantly worse than soft tissue arising

from the extremity. The poor outcome is not explained by the occurence of metastases but by local recurrence.

Study objective

To assess whether preoperative radiotherapy, as an adjunct to curative-intent surgery, improves the abdominal local recurrence-free survival.

Study design

Patient with histological proven RPS will be randomized between preoperative radiotherapy followed by surgery or surgery alone.

Intervention

Pre-operative radiotherapy with a dose of 50.4Gy in 28 fractions of 1.8Gy

Study burden and risks

The psychological burden caused by taking part of the clinical trial and also the possibility of more toxicity because of the radiotherapy, mainly gastro-intestinal toxicity, renal damage, hepatic damage and secundairy malignancies. Twenty-eight irradiation fractions will cause some physical distress.

Contacts

Public
European Organisation for Research in Treatment of Cancer (EORTC)

Avenue E. Mournier 83,bte 11
Brussel 1200
BE
Scientific
European Organisation for Research in Treatment of Cancer (EORTC)

Avenue E. Mournier 83,bte 11
Brussel 1200
BE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

*18 years old
WHO performance status * 2 (see Appendix C)
Primary untreated soft tissue sarcoma of retroperitoneal space or infra-peritoneal spaces of pelvis
Unifocal tumor
Histologically-proven RPS, see also exclusion criteria
Tumor both operable and suitable for radiotherapy (anticipated macroscopically complete resection, R0/R1 resection)
Patients must have American Society of Anesthesiologist (ASA) score * 2 (see Appendix G)
Normal renal function: Calculated creatinine clearance within normal value (calculated by Cockcroft-Gault; see Appendix E)
Functional contra-lateral kidney to the side involved by the RPS as assessed by intravenous pyelogram (done during the baseline CT-scan) or differential renal isotope scan
Normal bone marrow and hepatic function:
* White Blood cells * 2.5 x10 9 cells/L
* Platelets * 80 x10 9 cells/L
* Total bilirubin < 1.5 time the institutional upper limit normal of value (ULN)
Adequate cardiac function: less or equal to NYHA II (see Appendix D)
Normal 12 lead ECG (without clinically significant abnormalities)
Written informed consent

Exclusion criteria

Sarcoma originating from bone structure, abdominal or gynecological viscera
Multifocal disease or metastatic disease
Extension through the sciatic notch or across the diaphragm
The following diagnoses are excluded:
* Gastro-intestinal stromal tumor (GIST)
* Rhabdomyosarcomas
* PNET or other small round blue cells sarcoma, osteosarcoma or chondrosarcoma,
* aggressive fibromatosis

* sarcomatoid or metastatic carcinoma
Expected R2 resection
History of bowel obstruction or mesenteric ischemia or severe chronic inflammatory bowel disease
Pregnancy or breast feeding state (Female subjects who are breast feeding should discontinue nursing prior to the first day of study treatment and for at least 1 month after the surgery)
Co-existing malignancy within the last 5 years except for adequately treated basal cell carcinoma of the skin or carcinoma in situ of the cervix
Prior abdominal or pelvic irradiation for other prior malignancy or other disease
Presence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-01-2012
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	23-11-2011
Application type:	First submission

Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	31-10-2012
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	08-06-2015
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NCT01344018
CCMO	NL37929.031.11