Prevention of wound complications with hyperbaric oxygen therapy for soft tissue sarcoma patients

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22338

Source
NTR

Brief title
SHORT

Health condition

sarcoma, hyperbaric oxygen, preoperative radiotherapy

Sponsors and support

Primary sponsor: Erasmus Mc
Source(s) of monetary or material Support: Initiator

Intervention

Outcome measures

Primary outcome

The primary objective will be the number, size and features of postoperative wound complications during the first 4 months after surgery

Secondary outcome

- the acute toxicity during radiotherapy with HBOT according to the to the Common Terminology Crtiteria for Adverse Events 4 (CTC-AE4).

- the tumor response will also be evaluated with a MRI 2 weeks before the surgery according to the RECIST criteria.

- the percentage of necrosis in the pathology specimen.

Study description

Study objective

Our hypothesis is that HBOT decreases the incidence of wound complications of surgery following preoperative radiotherapy. Added to this, increasing the oxygen level of irradiated tissue might have a positive effect on radiotherapy response.

Study design

The patients will be followed up weekly during the first month, and monthly thereafter up to 4 months after surgery.

Intervention

Hyperbaric Oxygen, 90 minutes per , 5 days per week, during the radiotherapy course (25 fractions)

Contacts

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Eligibility criteria

Inclusion criteria

- Patients ¡Ý 18 years old

- Tumor size of > 5 cm.

- Primary tumour site: extremity, trunk, groin, (excluding intra-abdominal and retroperitoneal sarcomas)

- WHO performance status ¡Ü 2

- Written informed consent

- Absence of 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.

- Every patient has been discussed in the local tumor board.

- A MRI scan of the tumor not older than 6 weeks.

-CT thorax not older than 6 weeks.

- a resectable tumor according to the surgeon

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Other malignancy with a life expectancy of less than 2 years.

- Prior radiotherapy to the local site

- Presence of metastases

- Chemotherapy needed for this sarcoma

- Patients with contraindications for hyperbaric oxygen therapy: Pneumothorax, TBC, COPD Gold IV, bullae, myocardial infarction, EF 30%, serious cardiac valve problems, acute ischaemic CVA, unstable epilepsy.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-04-2016
Enrollment:	41
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL5571
NTR-old	NTR5693
CCMO	NL56437.078.16

Study results