

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

Gepubliceerd: 13-02-2016 Laatste bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22338

Bron

NTR

Verkorte titel

SHORT

Aandoening

sarcoma, hyperbaric oxygen, preoperative radiotherapy

Ondersteuning

Primaire sponsor: Erasmus Mc

Overige ondersteuning: Initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

J.J. Nuyttens
Erasmus MC, Daniel den Hoed,
Groenehilledijk 301,
Rotterdam 3075 EA
The Netherlands
+31 (0)10 7041766

Wetenschappelijk

J.J. Nuyttens
Erasmus MC, Daniel den Hoed,
Groenehilledijk 301,
Rotterdam 3075 EA
The Netherlands
+31 (0)10 7041766

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients ≥ 18 years old
- Tumor size of > 5 cm.
- Primary tumour site: extremity, trunk, groin, (excluding intra-abdominal and retroperitoneal sarcomas)
- WHO performance status ≤ 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	02-04-2016
Aantal proefpersonen:	41
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten