DOse REduction of preoperatieve radiotherapyin MYxoid liposarcoma.(Dosis verlaging van de preoperatieve bestraling van myxoidliposarcomen).

Published: 05-11-2010
Last updated: 24-03-2025

The induction of necrosis after reduced RT dose.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23428

Source
Nationaal Trial Register

Brief title
Doremy

Health condition

radiotherapy, myxoid liposarcoma, soft tissue sarcoma (radiotherapie, myxoid sarcomm en weke delen sarcoom)

Sponsors and support

Primary sponsor: NKI-AVL
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

The dose reduction will be regarded as a success if at least 90% of thus treated patients show at least 90% necrosis in the definitive resection specimen.

Secondary outcome

The aim is to provide a stopping rule for inefficacy of the new dose.

Study description

Background summary

To study whether a dose reduction of preoperative radiotherapy in MLS from 50Gy to 36Gy is equally effective in inducing extensive necrosis (thus maintaining comparable clinicopathological responses).

Study objective

The induction of necrosis after reduced RT dose.

Study design

1. Start inclusion 01-Jan-2011;
2. Finish 01-Jul-2012.

Intervention

To study whether a dose reduction of preoperative radiotherapy in MLS from 50Gy to 36Gy is equally effective in inducing extensive necrosis (thus maintaining comparable clinicopathological responses).

Contacts

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Eligibility criteria

Inclusion criteria

1. Age >18 years;
2. By biopsy proven myxoid sarcoma;
3. Performance score ECOG 0-2.

Exclusion criteria

1. Prior radiotherapy to target area;
2. Anticoagulant medication of any kind; especially Ascal (and derivates), coumarines, all heparin and heparin-like formulations;
3. Pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-01-2011
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion
Date: 05-11-2010

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47519
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2472
NTR-old	NTR2588
Other	: N10DMY
ISRCTN	ISRCTN wordt niet meer aangevraagd.
CCMO	NL33144.031.10
OMON	NL-OMON47519

Study results

Summary results
N/A