Arm function and quality of life after trimodal treatment of sulcus superior tumour (SST)

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Determine arm and shoulder function and quality of life scores before and after treatment of SST. The untreated extremity can serve as a control.Determine riskfactors for a poor functionale outcome and quality of life after treatment for SST (e.g....

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory tract neoplasms
Study type	Observational non invasive

Summary

ID

NL-OMON34727

Source
ToetsingOnline

Brief title
Armfunction after treatment for SST

Condition

- Respiratory tract neoplasms
- Respiratory tract therapeutic procedures

Synonym
Pancoast tumour

Research involving
Human

Sponsors and support

Primary sponsor: Heelkunde VUmc
Source(s) of monetary or material Support: Stichting chirurg en onderzoek;VUmc

Intervention

Keyword: Functional results, Lung carcinoma, Quality of life, Sulcus superior tumour

Outcome measures

Primary outcome

Questionnaire DASH (Disability of Arm, Shoulder and Hand)

Questionnaire Quality of life (SF-36)

Objective measurement of arm- and shoulderfunction (treated and untreated extremity)

A.R.A.-test: Action research arm-test

9-hole peg-test

R.O.M.-test: Range Of Motion-test

FAT-test: Frenchay Arm Test

Secondary outcome

Age

Symptomatic period before start treatment

Radiotherapy dose

chemotherapy scheme

clinical tumour stage (cTNM)

pathological tumour stage (pTNM)

Time interval between induction and surgery

Time interval between surgery and study date

Right or left handedness

Study description

Background summary

Superior sulcus tumours are rare lung carcinoma's classified as stage 2B or 3. With trimodality treatment (induction chemoradiotherapy, followed by surgery) patients have a relatively favouorable prognosis, especially compared to other stage 3 patients. However, the function of shoulder and arm and quality of life may be impaired due to the intensive local treatment. In the literature virtually no data are available on this topic. Since VUmc is a referral centre for patients with SST and since 2002 all patients have been treated with the same protocol, an ideal situation exists to evaluate the long term disabilities and quality of life after treatment.

Study objective

Determine arm and shoulder function and quality of life scores before and after treatment of SST. The untreated extremity can serve as a control.
Determine riskfactors for a poor functionale outcome and quality of life after treatment for SST (e.g. radiotherapydose, interval between induction and surgery, etc
To inform patients in the future before surgery on the expected function and quality of life after resection
If avoidable risk factors can be identified, e.g. through perioperative measures
Initiate new studies on safety of new treatment protocols (eg. higher radiotherapy doses)

Study design

Longitudinal cohort study in patients operated in VUmc aftter induction with chemoradiation for SST since 01-01-2002

Study burden and risks

Study will be scheduled on the same day as a outpatient clinic visit has been booked (if any). For patients who do not have a visit booked at VUmc, they will be asked to make a seperate appointment for this study. These participants will get a reimbursement of travel expenses.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Surgical resection of sulcus superior tumour in VUmc after induction treatment with chemoradiatiotherapy
Treated after 01-01-2002
Age at treatment between 18 and 80 years

Exclusion criteria

Current functional status ECOG >2 (confined to bed or chair >50% of waking hours)
Armfunction not assessable due to causes unrelated to locoregional treatment for SST (e.g. CVA, trauma, brain metastasis)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-04-2010
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	01-04-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL30761.029.09