Effectiveness of postoperative radiotherapy in patients with oral or oropharyngeal squamous cell carcinoma and histologically confirmed single ipsilateral lymphnode metastasis (pN1)

Published: 27-11-2007
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To determine the optimal therapy for patients with pT1-2 pN0 oral and oropharyngeal cancer

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metastases
Study type	Interventional

Summary

ID

NL-OMON30589

Source
ToetsingOnline

Brief title
Doësak pN1 study

Condition

- Metastases
- Head and neck therapeutic procedures

Synonym
head-neck cancer metastasis, oral cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Deutsche Forschngsgemeinschaft Projekt 224

Intervention

Keyword: nodal metastasis, oral cavity, radiotherapy, squamous cell carcinoma

Outcome measures

Primary outcome

5-year survival

Secondary outcome

Recurrence of tumour (local, regional, distant)

Quality of life

Treatment Costs

Study description

Background summary

No unanimous therapy advice exists for pT1-T2 oral and oropharyngeal cancers with a single neck-nodal metastasis (pN1). Until now postoperative irradiation is considered facultative.
Irradiation might improve 5-years survival but deteriorates quality of life

Study objective

To determine the optimal therapy for patients with pT1-2 pN0 oral and oropharyngeal cancer

Study design

Multi-centre (Europe) open 2-arm prospective randomised

Intervention

Postoperative Irradiation of the neck

Study burden and risks

Non-radiation arm : possible higher risk of tumour recurrence
Irradiation-Arm: 30 radiation-sessions with known adverse effects short-term (dermatitis and mucositis) and long term (fibrosis, higher risk of regional infection)

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

pT1/T2 oral or oropharyngeal cancer

pN1 nodal metastasis
Complete surgical resection
Patient agreement
Karnovsky > 50

Exclusion criteria

Pregnancy
< 18 years
Karnovsky <50
legally incapable

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-12-2012
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	27-11-2007
Application type:	First submission

Review commission: METC NedMec

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	NL16090.041.07