(Cost-)effectiveness of an interdisciplinary head and neck rehabilitation program compared to usual supportive care for head and neck cancer patients

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22076

Source
NTR

Brief title
P16HNR

Health condition

Head and neck cancer, quality of life, rehabilitation, return to work, societal participation

Hoofd-halskanker, kwaliteit van leven, revalidatie, terugkeer naar werk, maatschappelijke participatie

Sponsors and support

Primary sponsor: Netherlands Cancer Institute (NKI)
Source(s) of monetary or material Support: Funding study: Netherlands Cancer Institute
Funding authors Beck/Passchier/Stuiver: Non-restricted grant from ATOS Medical Sweden.

Intervention

Outcome measures

Primary outcome

- Health-related quality of life expressed in the EORTC QLQ-C30 summary score.

Secondary outcome

- Functional health-related quality of life

- Cost-effectiveness

- Return to work

- Societal participation

- Unmet needs of the patient

- Patient satisfaction

- Clinical outcomes (e.g. adverse events, hospital admissions)

Study description

Background summary

Introduction

Since 2011, a tailored, interdisciplinary head and neck rehabilitation (IHNR) program, covered by the basic healthcare insurance, is offered to advanced head and neck cancer (HNC) patients in the Netherlands Cancer Institute (NKI). This program is developed to preserve or restore patients' functioning, and to optimize health-related quality of life (HRQoL). It applies an integrated approach to define patients' individual goals and provide rehabilitation care throughout the cancer care continuum. The aim of the current study is to assess the (cost-) effectiveness of the IHNR approach compared to usual supportive care (USC) consisting of monodisciplinary and multidisciplinary care in advanced HNC patients.

Methods

This multicenter prospective observational study is designed to compare (cost-)effectiveness of the IHNR to USC for advanced HNC patients treated with chemoradiotherapy (CRT) or bioradiotherapy (BRT). The primary outcome is HRQoL represented in the EORTC QLQ-C30 summary score. Functional HRQoL, societal participation, utility values, return to work (RTW), unmet needs (UN), patient satisfaction and clinical outcomes are secondary outcomes, assessed using the EORTC QLQ-H&N35, USER-P, EQ-5D-5L, and study-specific questionnaires, respectively. Both patient groups are requested to complete the questionnaires at: diagnosis (baseline; T0), 3 months (T1), 6 months (T2), 9 months (T3) and 12 months (T4) after start of medical treatment. Differences in outcomes between the intervention and control group will be analyzed using mixed effects models, Chi-square test and descriptive statistics. In addition, a cost-effectiveness analysis (CEA) will be performed by means of a Markov decision model. The CEA will be performed using a societal perspective of the Netherlands.

Discussion

This prospective multicenter study will provide evidence on the effectiveness and cost-effectiveness of IHNR compared to USC. RTW and societal participation, included as secondary outcomes, have not been studied sufficiently yet in cancer rehabilitation. Interdisciplinary rehabilitation has not yet been implemented as usual care in all centers, which offers the opportunity to perform a controlled clinical study. If demonstrated to be (cost-) effectiveness, national provision of the program can probably be advised.

Study objective

First, we hypothesize that IHNR will shorten the time to regain (baseline) HRQoL.

Second, we hypothesize that the program will enhance the ability to resume work-related and daily activities, and will lead to a reduction in medical consumption (e.g. tube feeding) and adverse events (e.g. occurrence of pneumonias).

Third, we expect that these improvements will result in a reduction of hospital- and society-related costs, resulting in more cost-effectiveness compared to USC.

Study design

- Baseline: at diagnosis (T0)

- Follow-up: 3 (T1), 6 (T2), 9 (T3) and 12 (T4) months after start of oncological treatment

Intervention

- Intervention group: Interdisciplinary head and neck rehabilitation program (IHNR)

- Control group: Usual supportive care

Contacts

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Eligibility criteria

Inclusion criteria

- Patients (18 years or older) diagnosed with advanced head and neck squamous cell carcinoma (HNSCC; stage 3 and 4)

- Patients are treated with primary chemoradiotherapy (Cisplatin or Carboplatin) or bioradiotherapy (Cetuximab) with curative intent

Exclusion criteria

- Patients who are unwilling to cooperate

- Patients who are unable to take part in the program due to a language barrier or an interfering psychiatric or psychological disorder are excluded from the study

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2017
Enrollment:	128
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-04-2018
Application type:	First submission

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	NL6952
NTR-old	NTR7140
Other	METC van het Antoni van Leeuwenhoek : P16HNR

Study results

Summary results
Feasibility study of IHNR: PMID 26024692