

Effectiveness of lipofilling in patients with impaired speech and/or swallowing function after treatment for head and neck cancer

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The primary objective of this study is to evaluate the effectiveness of lipofilling in treatment of speech and swallowing impairment after treatment for head and neck cancer. The secondary objective is to evaluate the effect of lipofilling on tongue...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44636

Source

ToetsingOnline

Brief title

Lipofilling in patients with impaired speech and/or swallowing function

Condition

- Other condition

Synonym

Swallowing- and speech impairment

Health condition

Functionele aandoeningen (slik en spraakproblemen)

Research involving

Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Head and neck cancer, Lipofilling, Speech, Swallowing

Outcome measures

Primary outcome

Speech outcomes:

- Objective outcomes: Intelligibility, diadochokinesis, voice quality and vowel space.
- Subjective outcomes: Speech Handicap Index

Swallowing outcomes:

- Objective outcomes: Penetration-aspiration scale, residue after swallowing, Functional Oral Intake Scale en weight change.
- Subjective outcomes: EORTC QLQ-C30 en H&N35 en SWAL-QOL

Secondary outcome

Effect on tongue base volume, feasibility and patients' satisfaction.

Study description

Background summary

Treatment for head and neck cancer can lead to long-term functional impairments such as dysphagia and speech problems. In this case, patients the patient receives intensive therapy including behavioral swallowing rehabilitation from

the speech language pathologist. However, long-term functional impairment still occurs in some patients refractory to these rehabilitation techniques. Dysphagia is accompanied with comorbidity like aspiration pneumonia which, if left untreated, might result death. When patients with chronic, severe dysphagia often have no other options left, besides in some cases a functional total laryngectomy in which the airway and upper digestive tract are separated, lipofilling can be of potential value as *last resort* treatment. However, results regarding short- and long-term effectiveness are lacking.

Study objective

The primary objective of this study is to evaluate the effectiveness of lipofilling in treatment of speech and swallowing impairment after treatment for head and neck cancer. The secondary objective is to evaluate the effect of lipofilling on tongue (base) volume, feasibility and patient*s satisfaction.

Study design

Observational cohort study

Intervention

Lipofilling is a procedure wheren autologous fat is transplanted from the abdominal wall/thigh to throat/oral cavity.

Study burden and risks

The experimental nature of the treatment will be discussed in detail with the patient. The burden of this study consists of the possible complication of the procedure (which are expected to be low after experience with previous treated patients), as well as the time burden and minimal radiation risk of the videofluoroscopy.

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

Patients with chronic, refractory speech and/or swallowing problems after treatment for head and neck cancer

According to the rehabilitative care team, there is no other option except lipofilling

Exclusion criteria

-

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	27-11-2017
Enrollment:	19
Type:	Actual

Ethics review

Approved WMO	
Date:	14-09-2017
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	NL61727.031.17