Exercise therapy for trismus

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27855

Source
Nationaal Trial Register

Health condition

trismus
restricted mouth opening
mouth opening
head and neck cancer
head and neck neoplasms

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: University Medical Center Groningen

Intervention

Outcome measures

Primary outcome

Effects of exercise therapy as change in mouth opening (millimetres)

Secondary outcome

Experienced pain, limitations of mandibular function, quality of life, and patient satisfaction of stretching device.

Study description

Background summary

Patients treated for head and neck cancer often suffer from several adverse effects after oncological treatment, including a severely restricted mouth opening (trismus). Trismus impacts oral functioning (biting, chewing, laughing, yawning, drinking, kissing etc.) considerably and as a result also quality of life. In this randomized controlled trial, two stretching devices, the TheraBite® Jaw Motion Rehabilitation System™ (TheraBite) and the Dynasplint Trismus System® (DTS), will be compared regarding the increase in mouth opening in head and neck cancer patients with a severely restricted mouth opening. Secondary outcome variables are oral functioning and quality of life.

Study objective

Increase in mouth opening after exercise treatment using the following stretching devices: the TheraBite or Dynasplint.

Study design

week 0, 3, 6, 12, 26.

Intervention

DTS: 1 stretch per session, 3 times a day for 30 minutes. (a total of 90 minutes a day)

TheraBite: 20 stretches per session, 6 times a day, 30 seconds OR 30 stretches per session, 4 times a day, 30 seconds. (a total of 60 minutes a day

Contacts

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Eligibility criteria

Inclusion criteria

Patients (1) are at least 18 years, (2) received treatment concerning head and neck cancer (including surgery, radiotherapy and chemotherapy) (3) have a maximal mouth opening of 35 millimeter or less.

Exclusion criteria

Patients diagnosed with osteoporosis or osteonecrosis or severe periodontitis, have oral abscesses or other infectious processes in the head and neck region, have a recurrence or metastases in the head and neck region.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial

Control: Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2016
Enrollment:	60
Type:	Actual

Ethics review

Positive opinion

Date:	05-12-2015
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	NL4176
NTR-old	NTR5589
Other	54802 : ABR

Study results