Radiotherapy to major salivary glands in patients with parkinsonism and severe drooling.

Published: 26-05-2010
Last updated: 02-05-2024

Hypotheses:1. RTX to the salivary glands is a safe and effective treatment of sialorrhoea; 2. RTX to the submandibular glands is at least as effective as RTX to parotid glands 3. RTX to submandibular glands causes less adverse events than RTX to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON34663

Source
ToetsingOnline

Brief title
The effect of radiotherapy on drooling

Condition

- Movement disorders (incl parkinsonism)

Synonym
Drooling, Sialorrhoea

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Princes Beatrix Fonds

Intervention

Keyword: Drooling, Parkinsonism, Radiotherapy, Salivary glands

Outcome measures

Primary outcome

The score on item 6 of the ADL-section of the Unified Parkinson*s Disease

Rating Scale (UPDRS) will be used as primary endpoint.

Secondary outcome

The clinical global impression scale (CGI), the semi-quantitative Drooling

Quotient (DQ) and the *swab method* will serve as secondary endpoints, as well

as a structured adverse event questionnaire.

Study description

Background summary

Sialorrhoea or drooling causes physical and emotional problems, impairing the quality of life. Approximately 80% of patients with Parkinson*s disease suffer from sialorrhoea due to swallowing dysfunction. Current therapies are complicated by adverse events, limited duration of effect or invasiveness. In a follow-up study, radiotherapy (RTX) to parotid glands was shown to be an effective, safe long-term treatment for parkinsonism patients. However, increased viscosity of saliva was an inconvenient complication in several patients. Both from a theoretical (submandibular saliva is the main source of resting saliva) and clinical view (submandibular saliva is viscous, parotid saliva is watery), RTX to submandibular glands instead of parotid glands may reduce this complication and may show to be more effective in treating drooling. Unfortunately, no placebo-controlled studies on the efficacy and safety of RTX to the salivary glands for this humiliating problem in patients with parkinsonism are yet available in the literature.

Study objective

Hypotheses:
1. RTX to the salivary glands is a safe and effective treatment of sialorrhoea;
2. RTX to the submandibular glands is at least as effective as RTX to parotid

glands
3. RTX to submandibular glands causes less adverse events than RTX to parotid glands

Study design

A prospective, double-blind, randomised, placebo-controlled trial, will be performed in 45 patients with parkinsonism suffering from severe sialorrhoea. Patients will be divided into 3 equally sized groups treated by, respectively, placebo-RTX (1), RTX to both parotid glands (2) and RTX (3) to both submandibular glands. Severity of sialorrhoea will be evaluated at 1, 3, 6 and 12 months post-treatment, using subjective and objective outcome measures. Inter- and intra-group efficacy of the various treatments and adverse events of therapy will be analysed.
The placebo-group will receive radiotherapy after 6 months and they will also be evaluated at 6 months post-treatment.

Intervention

Radiotherapy to the parotid, submandibular glands or placebo-radiotherapy.

Study burden and risks

In a follow-up study, radiotherapy (RTX) to parotid glands was shown to be an effective, safe long-term treatment for parkinsonism patients.
Also 3 studies report about the role of RTX for sialorrhoea in patients with neurodegenerative disorders and describe good results concerning efficacy and safety.
The risk of inducing secondary malignancy by radiotherapy is less than 1% and since most patients are in advances stage of disease with limited life expectancy.
This study tries to establish the efficiacy and safety of RTX as an important treatment of sialorrhoea. therfore the field of movement disorders will hopefully benefit from the results of this research.

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

Inclusion criteria are:
1. Clinical symptoms of parkinsonism
2. A diagnosis of severe sialorrhoea (score 3 or 4 on item 6 of the Activities of Daily Living (ADL) section of the Unified Parkinson*s Disease Rating Scale (UPDRS))
3. Written informed consent obtained from the patient
4. All patients must be older than 50 years of age

Exclusion criteria

Exclusion criteria are:
1. Concurrent participation in another investigational study.
2. The use of drugs, like anticholinergic drugs, that interfere with saliva secretion.
3. Previous surgical procedures in the oral or nasal cavity interfering with saliva production.
4. A history of (pre)malignancy in the radiation treatment portal.
5. Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-05-2010
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO

Date:	26-05-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL30440.042.10