Inhibition of salivary glands to reduce uptake of radioactive Iodine

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Primary: to determine if inhibition with GPB can provide a significant (>30%) reduction in the accumulation of orally administered Iodine-123 in salivary glands, measured at 4h after administraion. Secondary: to determine if a reduction at 4h...

Ethical review	Approved WMO
Status	Pending
Health condition type	Thyroid gland disorders
Study type	Interventional

Summary

ID

NL-OMON46303

Source
ToetsingOnline

Brief title
Inhibition of Salivary glands for radioactive Iodine

Condition

- Thyroid gland disorders
- Salivary gland conditions

Synonym
Iodine accumulation in salivary glands., Iodine biodistribution

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: KWF

Intervention

Keyword: Anticholinergic inhibition, Radioactive Iodine, Salivary glands

Outcome measures

Primary outcome

The primary parameter is the total quantified uptake of Iodine-123 on planar scintigraphy in all macroscopic salivary glands together (with and without GPB) measured at 4h after administration.

Secondary outcome

Secondary parameters are the uptake in salivary glands at 24h, uptake in stomach and bowels, and uptake in other normal tissues throughout the body.

Study description

Background summary

After multiple Iodine-131 treatments, patients can be confronted with persistent xerostomia and reduced quality of life. Salivation can be inhibited with anticholinergic / antimuscarinergic pharmaceuticals. Glycopyrronium bromide (GPB) inhibits salivary glands and prevents vasodilatation of afferent vasculature. We therefore assume that inhibition with GPB will lead to reduced accumulation of Iodine in salivary glands, and thus may be able to prevent xerostomia in patients treated with Iodine-131.

Study objective

Primary: to determine if inhibition with GPB can provide a significant (>30%) reduction in the accumulation of orally administered Iodine-123 in salivary glands, measured at 4h after administraion. Secondary: to determine if a reduction at 4h persists at 24h, if accumulation in the stomach can also be reduced, if the uptake in other normal organs is influenced, and (conditionally) if a half dose GPB can also provide the desired effect.

Study design

Single center prospective interventional phase II study.

Intervention

Pharmaceutical intervention is one intramuscular administration of 0.4 mg GPB (conditionally 0.2 mg after the first 5 patients). Diagnostic interventions are two Iodine-123 imaging procedures (one without GPB and one with GPB), at least one week apart.

Study burden and risks

Participation in this study has no significant risks. Participation does not induce a delay in diagnosis or treatment. A single intramuscular administration of 0.4 mg GPB may induce temporary side effects related to the desired effect (dry mouth, dry skin) and a low risk of general side effects like feeling drowsy or tachycardia. Patients will receive two Iodine-123 imaging procedures (with at least 1 week interval), which both involve intravenous administration of 18,5 MBq Iodine-123 followed planar scintigraphic imaging of the head-neck area from anterior and posterior at 4h and 24 after administration. This provides a very limited radiation dose in the absence of functional thyoid tissue. The estimated radiation dose of participation is 2 administrations x 18,5 MBq x 0,011 mSv/MBq = 0,4 mSv in total. This dose is well below the range of normal diagnostic procedures and does not induce a significant risk, especially not in this population in follow-up after high-dose Iodine-131 treatment for thyroid carcinoma.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066 CX
NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- In follow-up after treatment for thyroid carcinoma
- Received only one treatment with Iodine-131
- Currently no signs of recurrence

Exclusion criteria

- Age < 18y
- Inability to provide informed consent
- Planned changes in treatment/medication between the baseline scan and intervention scan
- History of disease or treatment involving the salivary glands (Malignant or benign tumour, sialoadenitis, stone, surgery, SLE, RT to head-neck, etc)
- Currently on anticholinergic medication
- Contra-indications for anticholinergic medication (Glaucoma, obstructed digestive/urological tract, megacolon, ileus, tardive dyskinesia)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2018
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Robinul for injection (Biosyn artzneimittel GmbH)
Generic name:	Glycopyrrhonium bromide

Ethics review

Approved WMO

Date:	11-01-2019
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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
EudraCT	EUCTR2018-002341-10-NL

Register	ID
CCMO	NL66414.031.18