Taste and smell dysfunction in patients more than two years after start of immune checkpoint inhibitor therapy

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To determine the prevalence of taste and smell dysfunction in patients more than two years after start of ICI therapy - compared with a control group of caregivers. Secondary objective: to assess the association between taste and smell dysfunction,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON53895

Source
ToetsingOnline

Brief title
Taste-SPICIER

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer, malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Immune checkpoint inhibitor therapy, Oncology, Smell, Taste

Outcome measures

Primary outcome

Taste and smell dysfunction, measured using taste strips and Sniffin* Sticks.

Secondary outcome

Salivary flow rate, salivary pH. proteins and electrolytes, xerostomia, and

perceived taste and smell dysfunction and impact of taste and smell

dysfunction.

Study description

Background summary

Immune checkpoint inhibitors (ICIs) are widely used as treatment for multiple cancer types and the number of patients with long-term disease control after ICIs is increasing. However, the use of ICIs is associated with adverse events (AEs) which can have a negative impact on quality of life (QoL). These AEs include oral manifestations, like alterations in taste and smell, xerostomia, and oral mucosal disorders, and could lead to unwanted weight loss. However, the characteristics of taste and smell dysfunction and xerostomia after treatment with ICIs are unknown. More insight in this phenomenon should be gained to make health care professionals aware of this problem to help patients cope with these AEs.

Study objective

To determine the prevalence of taste and smell dysfunction in patients more than two years after start of ICI therapy - compared with a control group of caregivers.

Secondary objective: to assess the association between taste and smell dysfunction, and saliva secretion rate, saliva composition (pH, electrolyte and protein composition) and subjective feeling of a dry mouth (xerostomia) in patients more than two years after start of ICI therapy - compared with a

control group of caregivers.

Study design

Observational cross-sectional study.

Study burden and risks

Participation in the study will include one study visit of approximately 1,5 hours. If possible, the study visit will be combined with a regular follow-up visit. In this study, no invasive procedures will be performed.

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

1. Patient with melanoma, NSCLC or urogenital cancers >= 2 years since treatment with at least one cycle of immune checkpoint inhibitor (CTLA-4 inhibitor, PD-(L)1 inhibitor, or both) within the Department of Medical Oncology or Pulmonary Oncology of the UMCG.
2. Age >=18 years at time of immune checkpoint inhibitor treatment
3. Understand or abide to the study procedures
4. Have given informed consent

A caregiver must meet all of the following criteria:
1. Age >=18 years
2. Understand or abide to the study procedures
3. Have given informed consent

Exclusion criteria

1. As previous or subsequent therapies, only surgery and palliative radiotherapy is allowed (excluding radiotherapy in the head-neck and brain region)
2. Previous treatment in the past ten years for malignancy other than melanoma (excluding non-melanoma skin cancer, cervical intra-epithelial neoplasia (CIN) or carcinoma in situ of breast) (for patients: other than current malignancy)
3. History of ear-nose-throat disease or auto-immune disorder affecting taste, smell, mouth mucosa, or saliva production (for patients: before start ICI)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-10-2023
Enrollment:	0
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	13-09-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	25-03-2024
Application type:	Amendment
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	NL81573.042.22