Taste and smell disturbances in patients with gastrointestinal stromal tumors using tyrosine-kinase inhibitors.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21230

Source
NTR

Brief title
TBA

Health condition

Gastro-intestinal stromal tumors

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

What is the prevalence of taste and smell disturbances in GIST patients using TKIs?

Secondary outcome

What is the type of taste and smell disturbances in GIST patients using TKIs?
What is the association between taste and smell disturbances and impact on daily life and QoL?
What are the differences between imatinib, sunitinib and regorafenib in taste and smell disturbances?
What is the association between taste and smell disturbances and the duration of the TKI use?

Study description

Background summary

This study will be conducted at the University Medical Center Groningen (UMCG). Patients who are currently treated with a TKI for a GIST and understand spoken and written Dutch will be included. Fifty eligible patients will be asked to participate. At this moment, around fifty patients are currently treated with TKIs for a GIST at the UMCG. Based on a recent study on taste alterations in oncological patients receiving systemic therapy, it is expected that this number is sufficient to provide meaningful data. The potential participants are derived from the patient database of the Dutch GIST registry that is open for all patients diagnosed with a GIST. Potential participants will be screened in the objection registry of the UMCG. Patients who are registered will not be invited to participate in this study. Patients who are not registered will be send a letter that explains the study design and mentions that they will receive a telephone call. The potential participants will be asked to answer questions regarding taste disturbances by phone. This call will last approximately fifteen minutes. At any moment, they can decide to withdraw from the study. When patients pick up the phone, they will be asked explicitly for consent to participate. If consents is given, participants will answer the questionnaire.
The questionnaire that is used in this study (see supplement) is based on two previously used questionnaires which, respectively, were designed 1) to study metallic taste in patients who undergo systemic cancer therapy and 2) to study the impact of taste and smell alterations on the liking of specific nutritional supplements during systemic anti-cancer therapy. Information about the medical history of the patients and their current use of TKIs will be collected from the patients electronic file after the phone call and will not be part of the questionnaire.
The primary outcome of this questionnaire will be the proportion of patients reporting taste and smell alterations. The secondary outcome will be data on the type of taste disturbances and in particular alterations of bitter, sweet, salt, sour, metallic and a continuous taste. Furthermore, insight in the relation with the impact on daily life and QoL of the participants will be provided.

Study objective

It is hypothesized that taste and smell disturbances are common among GIST patients using TKIs.

Study design

Start July 15, finish December 1 - 2019

Intervention

Patients will be interviewed by phone about taste alterations. Information about the background of the patients, including gender, age and type and treatment of the GIST, will be collected from the patients electronic file.

Contacts

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Eligibility criteria

Inclusion criteria

- Pathologically confirmed diagnosis of a GIST
- Currently treated with imatinib, sunitinib or regorafenib
- Able to understand spoken and written Dutch
- Ability to comprehend and complete questionnaire by phone
- > 18 years

Exclusion criteria

- No oral food intake
- Coexisting-morbidities affecting taste or smell function
- Uncertainty about the willingness or ability of the patient to comply with the protocol requirements

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-07-2019
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	25-06-2019
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	NL7827
Other	METc UMCG : METc 2019/360

Study results