

# Taste and smell changes in testicular cancer patients treated with cisplatin based chemotherapy

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Primary Objective: To investigate the nature, prevalence, and duration of taste and smell changes in patients with disseminated testicular cancer treated with cisplatin based chemotherapy (BEP or EP).Secondary Objective(s): -To explore the short-...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON37350

### Source

ToetsingOnline

### Brief title

Taste, smell, and chemotherapy (TASTY)

### Condition

- Other condition
- Reproductive neoplasms male malignant and unspecified

### Synonym

taste and smell

### Health condition

smaak- en geurfunctie

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** Campina, Nutricia, Top Institute Food and Nutrition

## Intervention

**Keyword:** Cancer, Nutrition, Smell, Taste

## Outcome measures

### Primary outcome

Scores of gustatory and olfactory function of patients with disseminated testicular cancer treated with cisplatin based chemotherapy will be investigated using physiological tests (taste strips and \*Sniffin\* Sticks\*) and using a questionnaire on taste and smell function to investigate the subjective perception of taste and smell function among these patients. During the chemotherapeutic treatment the measurements will be re-assessed several times to investigate possible changes in gustatory and olfactory function before, during and after chemotherapy. Measurements will also be carried out 1, 3, 5 and 7 years after chemotherapy to investigate possible changes in gustatory and olfactory function in the long-term.

### Secondary outcome

The secondary parameters are food preference, dietary intake, quality of life, BMI, body composition (bone and fat mass), audiograms, BRS, blood glucose level and DNA. We will focus on changes in these parameters due to changes in gustatory and olfactory function as a consequence of chemotherapy.

# Study description

## Background summary

Taste and smell abnormalities are common in cancer patients undergoing chemotherapy, with a prevalence ranging from 46% to 77% for taste changes, and 35% to 75% for smell changes. These chemosensory changes are distressing for patients and can lead to changes in appetite, food choice, and nutrient intake. These changes can result in malnutrition and weight loss. Possibly, also unhealthy eating patterns can be developed due to these taste and smell changes, given the high prevalence of obesity among survivors of certain cancer types.

## Study objective

Primary Objective:

To investigate the nature, prevalence, and duration of taste and smell changes in patients with disseminated testicular cancer treated with cisplatin based chemotherapy (BEP or EP).

Secondary Objective(s):

- To explore the short- and long-term consequences of taste and smell changes in relation to food preference, dietary intake, and quality of life in patients with disseminated testicular cancer treated with cisplatin based chemotherapy.
- To investigate the appreciation of (medical) food products in patients with disseminated testicular cancer treated with cisplatin based chemotherapy.

## Study design

The present study will have a longitudinal (with measurements before the first chemotherapy, on day 7 of the first course, before the second course, on day 7 of the second course, 1 month after start of the last course, 7 months after the start of chemotherapy, and 1 year after the start of chemotherapy) and a cross-sectional (with measurements 1, 3, 5 and 7 years after chemotherapy) design. Patients can start participation in this study before the start of their chemotherapy, which will result in longitudinal data of these patients or they can start participation years after treatment, resulting in cross-sectional data.

## Study burden and risks

Performing the measurements, and filling out the questionnaires is considered as a minimal burden for the testicular cancer patients. With this study we hope to get insight into the nature, prevalence, and duration of taste and smell changes and their significance for food preference, dietary intake and quality

of life. With knowledge regarding taste and smell changes, a better prediction on food acceptance can be given at the start, during, and after chemotherapy to maintain a healthy eating pattern or, if necessary, improve the diet. Besides, this research will yield valuable information for industry with regard to further research and development in (medical) food products.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

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

### Inclusion criteria

Cancer patients:

- Testicular cancer patients treated with cisplatin based chemotherapy
  - Age range 18-50
  - Ability to comprehend Dutch (both reading and writing)
  - Signed informed consent;
- Healthy controls:

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- Healthy males
- Age 18-50 years
- Ability to comprehend Dutch (both reading and writing)
- Signed informed consent

## Exclusion criteria

Cancer patients

- Mental disability
- Smoking (cross-sectional part);Healthy controls:
- Mental disability
- Ever diagnosed with cancer
- History of taste and smell abnormalities
- Smoking (cross-sectional part)

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	10-07-2012
Enrollment:	140
Type:	Actual

## Ethics review

Approved WMO

Date:	12-04-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	30-01-2013
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	NL38757.042.11