# Prophylactic oral glutamine for docetaxel or paclitaxel associated taste alterations in cancer patients: a randomised, placebo-controlled, double-blind study

| Submission date                  | Recruitment status                    | <ul><li>Prospectively registered</li></ul> |
|----------------------------------|---------------------------------------|--|
| 01/10/2007                       | No longer recruiting                  | ☐ Protocol                                 |
| Registration date                | Overall study status                  | Statistical analysis plan                  |
| 30/10/2007                       | Completed                             | [X] Results                                |
| <b>Last Edited</b><br>10/06/2021 | Condition category Signs and Symptoms | [] Individual participant data             |
| 10/00/2021                       | Digita dila Dyniptonia                |  |

#### Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

#### Contact name

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## Additional identifiers

#### Protocol serial number

SG 239 /03

# Study information

#### Scientific Title

Prophylactic oral glutamine for docetaxel or paclitaxel associated taste alterations in cancer patients: a randomised, placebo-controlled, double-blind study

#### **Study objectives**

Patients with first taxane-based chemotherapy having a prophylaxis with oral glutamine have significantly less patient-perceived and objective taste alterations than those with placebo.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics Committee of the Canton St.Gallen, Switzerland. Approved on January 13th 2004 (ref: EKSG 03/080; Swissmedic 2004DR3015)

#### Study design

Single-center, randomized, double-blind, placebo-controlled, two-arm, parallel study.

#### Primary study design

Interventional

#### Study type(s)

Prevention

#### Health condition(s) or problem(s) studied

Taxane-associated dysgeusia

#### **Interventions**

The participants were randomly allocated to the following two arms:

Intervention arm: Glutamine (oral) 30 g per day in 2-3 doses Control arm: Maltodextrin (as placebo) 30 g per day in 2-3 doses

The interventions for both groups started on the first day of the taxane-based chemotherapy.

Expected duration of intervention for 2 cycles of taxane-based chemotherapy 6-8 weeks, extension encouraged to 3 months.

#### **Intervention Type**

Drug

#### Phase

**Not Specified** 

#### Drug/device/biological/vaccine name(s)

Glutamine

#### Primary outcome(s)

Taste alteration (dysgeusia), reported daily by the patient at the same time of the day (usually before dinner) answering the question Presently my sense of taste is ... using a Visual Analogue Scale (VAS: 0 mm = very good; 100 mm = very bad).

#### Key secondary outcome(s))

- 1. Taste recognition test, carried out at baseline, on day one of each chemotherapy cycle, and in addition on day 8 of the second chemotherapy cycle.
- 2. Adverse events

#### Completion date

31/03/2006

# Eligibility

#### Key inclusion criteria

- 1. Adult patients with cancer receiving for the first time a taxane-containing chemotherapy
- 2. Written informed consent
- 3. Able to feed themselves
- 4. Eastern Cooperative Oncology Group (ECOG) PS 2 or less

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

Αll

#### Total final enrolment

52

#### Key exclusion criteria

- 1. Previous surgery or radiotherapy of the oral or nasal region
- 2. Oral candidiasis
- 3. Zinc deficiency
- 4. Creatinine clearance of greater than or equal to 30 ml/min

#### Date of first enrolment

01/03/2004

#### Date of final enrolment

31/03/2006

## Locations

#### Countries of recruitment

Study participating centre
Head of Oncological Palliative Medicine
St.Gallen
Switzerland
9007

# Sponsor information

#### Organisation

Cantonal Hospital St.Gallen (Switzerland)

# Funder(s)

#### Funder type

Industry

#### **Funder Name**

Swiss Group for Clinical Cancer Research (SIAK): Pilot development grant

#### Funder Name

Eastern Switzerland Foundation of Clinical Cancer Research (OSKK)

#### **Funder Name**

Baxter Switzerland (unrestricted grant)

## **Results and Publications**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results article01/03/200810/06/2021YesNo