

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

Submission date 01/10/2007	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 30/10/2007	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 10/06/2021	Condition category Signs and Symptoms	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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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)

Primary study design

Interventional

Study design

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

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

All

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

Switzerland

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 type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2008	10/06/2021	Yes	No