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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

Registration date
30/10/2007

Overall study status
Completed

Last Edited
10/06/2021

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Florian Strasser

Contact details
Head of Oncological Palliative Medicine
Oncology Section
Department of Internal Medicine and Palliative Care Centre
Department of Interdisciplinary Medical Services
Cantonal Hospital
Rorschacherstrasse 95
St.Gallen
Switzerland
9007

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

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 measure
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).

Secondary outcome measures
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

Overall study start date
01/03/2004

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

Age group
Adult

Sex
Both

Target number of participants
60

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)

Sponsor details
Rorschacherstrasse 95
St. Gallen
Switzerland
9007
-
florian.strasser@kssg.ch

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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