The effect of stopping the H2-antagonist ranitidine in premedication regimens during paclitaxel treatment: ‘The RANISTOP study’

No registrations found.

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

Summary

ID

NL-OMON24209

Source
Nationaal Trial Register

Brief title
RANISTOP

Health condition

Allergy / anaphylaxis

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

The primary outcome will be the percentage (%) of patients who experience an HSR CTCAE

grade 3, 4 or 5 caused by paclitaxel infusion, grade determined prospectively by the oncology medical staff.

Secondary outcome

Secondary outcome parameters will be the severity of the HSR, grades as defined by CTCAE (version 4.0); the number of paclitaxel dosages (n) until first HSR occurrence and the cumulative dose of paclitaxel (mg/m2) at the moment of HSR occurrence.

Study description

Background summary

Rationale: Paclitaxel is one of the most commonly used medicines for cancer worldwide. It is used for treatment of breast-, ovarium-, and lung cancer, among others. Hypersensitivity reactions (HSR) are seen as a side effect during paclitaxel infusion in up to 20% of all patients. HSR can range from erythematous rashes to severe anaphylaxis. To prevent HSR, premedication prior to paclitaxel infusion is necessary and standard of care.
Ranitidine, a histamine 2 (H2)-antagonist, is registered for gastroduodenal reflux and ulcer disease. It has been given for years as standard of care premedication along with a histamine 1 (H1)-antagonist (clemastine) and a corticosteroid (dexamethasone) to prevent HSR caused by paclitaxel infusion. This standard premedication regimen was based on similar regimens that were used in preventing HSR to radiographic contrast media (RCM). The added value of a H2-antagonist to the premedication regimen has never been confirmed. Greenberger et al. showed that the H2-antagonist cimetidine (which has similar pharmacological properties as ranitidine) was not effective in the prevention of HSR caused by RCM. In addition, clinical studies and several case reports have shown that ranitidine gives an additional risk of side effects such as abnormal liver enzyme levels, nausea, vomiting, skin rash and HSR.
Therefore, in 2019, ranitidine will be removed from the premedication regimens given to patients receiving paclitaxel in the Erasmus MC. In this study the effect of this change in policy on HSR incidence during paclitaxel treatment in cancer patients will be evaluated.
Objective: To evaluate the effect of a policy change regarding the premedication scheme on the incidence of HSR during paclitaxel based chemotherapy, specifically the incidence of clinically relevant HSR (grade ≥3 as per Common Terminology Criteria for Adverse Events; CTCAE version 4.0) during paclitaxel-based chemotherapy with a premedication regimen with ranitidine compared to a premedication regimen without ranitidine.
Secondary objectives are to determine the severity (grade) of paclitaxel-induced HSR as defined by CTCAE (version 4.0) with and without ranitidine; to determine the number of paclitaxel dosages until first HSR occurrence with and without ranitidine and to determine the cumulative dose of paclitaxel at the moment of HSR occurrence with and without ranitidine.
Study design: This is a before-after study.
Study population: Paclitaxel-induced HSR incidence in 366 patients with solid tumours for whom paclitaxel based chemotherapy is considered standard treatment will be evaluated.
Main study parameters/endpoints: The primary outcome will be the percentage (%) of

patients who experience an HSR CTCAE grade 3, 4 or 5 caused by paclitaxel infusion, grade determined prospectively by the oncology medical staff. Secondary outcome parameters will be the severity of the HSR, grades as defined by CTCAE (version 4.0); the number of paclitaxel dosages (n) until first HSR occurrence and the cumulative dose of paclitaxel (mg/m2) at the moment of HSR occurrence.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will be treated with paclitaxel as standard of care. They will be admitted to the outpatient clinic conform standard of care and premedication will be given in the standard regimen with ranitidine ('before intervention') and in a regimen without ranitidine ('after intervention'). We will carefully observe all included patients, during the whole study period, conform standard of care.

Study objective

Ranitidine has no added value in preventing a paclitaxel induced hypersensitivy reaction

Study design

2018-Apr-17 inclusion of first patient, 25-11-2019 inclusion of 366 patients, January 2020 analysis and end of study.

Intervention

Removal of ranitidine from the paclitaxel premedication regimen

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a patient must meet the following criteria:
- Age ≥18 years;
- Planned treatment with regular paclitaxel based chemotherapy for any indication and with any dose.

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded in this study:
- Prior treatment with a paclitaxel-based regimen;nal reflux and ulcer disease.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-04-2018
Enrollment:	366
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
no plan available yet

Ethics review

Positive opinion

Date:	25-10-2019
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	NL8173
Other	METC EMC : MEC-2018-1499

Study results

Summary results
NA