Absorption of sublingually delivered fentanyl (Abstral®) in head and neck cancer patients treated with curatively aimed chemo-radiotherapy

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26436

Source
NTR

Health condition

head and neck cancer, radiochemotherapy, mucositis, fentanyl

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Prostrakan

Intervention

Outcome measures

Primary outcome

Fentanyl pharmacokinetics (i.e.clearance, AUC).

Secondary outcome

-Side effects conform the CTCAE 4.03 toxicity criteria

-Mucositis according the CTCAE 4.03 toxicity criteria and the OMAS

-Painscores, scored with the NRS (in patients with pain)

-Xerostomia using the GRIX

Study description

Background summary

SUMMARY

Rationale: The majority of head and neck cancer patients treated with curatively aimed chemoradiotherapy suffer from severe mucositis. Mucositis can cause different problems e.g. pain and difficulties with swallowing. Furthermore, xerostomia often occurs after chemoradiotherapy, due to destruction of the salivary glands. From the third week of radiotherapy, oral pain is getting worse, and will require analgesics. Mucositis is increasing in the weeks following and worst at the end of the radiotherapy treatment. Most patients need strong opioids for the treatment of the pain caused by mucositis. Fentanyl is a widely used strong opioïd and is highly lipophilic. Nowadays there are several immediate release fentanyl products for the treatment of breakthrough pain. One of them is sublingually delivered fentanyl, (Abstral ®). Abstral is placed directly under the tongue to be absorbed by the mucosa. It is unknown if mucositis and xerostomia will influence the absorption of sublingual fentanyl and thereby its potential efficacy in case of breakthrough pain.

Objective: First objective: To study the influence of mucositis on the absorption of sublingually delivered fentanyl (Abstral ®) in head and neck cancer patients treated with chemoradiotherapy. Secondary objectives: to study the influence of xerostomia on the absorption of sublingually delivered fentanyl (Abstral®) in these patients 6 weeks after treatment with chemoradiotherapy; to study the relation between the dose of radiotherapy administered sublingually and the changes in pharmacokinetics of sublingually delivered fentanyl (Abstral®); and to study the effect of sublingually delivered fentanyl (Abstral®) on pain intensity in these patients before, during and after chemoradiotherapy.

Study objective

First objective: To study the influence of mucositis on the absorption of sublingually delivered fentanyl (Abstral ®) in head and neck cancer patients treated with chemoradiotherapy.

Secondary objectives: to study the influence of xerostomia on the absorption of sublingually delivered fentanyl (Abstral®) in these patients 6 weeks after treatment with chemoradiotherapy; to study the relation between the dose of radiotherapy administered sublingually and the changes in pharmacokinetics of sublingually delivered fentanyl (Abstral®); and to study the effect of sublingually delivered fentanyl (Abstral®) on pain intensity in these patients before, during and after chemoradiotherapy.

Study design

4 different time points: 24-72 hrs before the start of the chemoradiotherapy (T=0), 24-72 hrs before the planned start of the 2nd gift of chemotherapy (T=1) , 24-72 hrs before the planned start of the 3rd gift of chemotherapy (T=2) and six weeks after the end of the chemoradiotherapy (T=last).

Intervention

Patients will be given a single dose of Abstral® 200 mcg sublingually. Pharmacokinetics of sublingually delivered fentanyl will be measured at 4 different time points: 24-72 hrs before the start of the chemoradiotherapy (T=0), 24-72 hrs before the planned start of the 2nd gift of chemotherapy (T=1) , 24-72 hrs before the planned start of the 3rd gift of chemotherapy (T=2) and six weeks after the end of the chemoradiotherapy (T=last).

Contacts

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Eligibility criteria

Inclusion criteria

•patients with histologically confirmed head and neck cancer and planned treatment with radiotherapy in combination with cisplatin chemotherapy
•written informed consent
•18 years or older

Exclusion criteria

•use of fentanyl medication within one week before inclusion in the study (other opioid and non-opioid analgesics are allowed)
•opioid intolerance
•former allergic reactions to opioids
•serious psychiatric illness, confusion or intellectual disability

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2014
Enrollment:	14
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-02-2015
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	NL4741
NTR-old	NTR4995
Other	: MEC 2013-550

Study results