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

Gepubliceerd: 18-02-2015 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26436

Bron
NTR

Aandoening

head and neck cancer, radiochemotherapy, mucositis, fentanyl

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: Prostrakan

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

•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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

•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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2014
Aantal proefpersonen:	14
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-02-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4741
NTR-old	NTR4995
Ander register	: MEC 2013-550

Resultaten