Clinical pharmacokinetics of Rapid Onset Opioids in patients with breakthrough cancer pain. A crossover study of intranasal and sublingual fentanyl

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To determine and compare PK profiles of two of the most used ROOs in cancer patients: one intranasal fentanyl formulation (INFC, Instanyl®) and one sublingual fentanyl formulation (SLF, Abstral®).

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44451

Source
ToetsingOnline

Brief title
PHAROO

Condition

- Other condition
- Metastases

Synonym
BTcP, pain in cancer

Health condition

doorbraakpijn bij kanker

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Reinier de Graaf Groep

Intervention

Keyword: breakthrough cancer pain (BTcP), fentanyl, pharmacokinetics, rapid onset

Outcome measures

Primary outcome

The determination of pharmacokinetic parameters of two transmucosal fentanyl

products in patients with breakthrough cancer pain in a crossover design.

Secondary outcome

Secundary study parameters are efficacy through pain intensity scores and

patients* preference.

Study description

Background summary

For the treatment of breakthrough cancer pain there are six transmucosal fentanyl products, also called rapid onset opioids (ROOs), available on the Dutch market (Actiq, Instanyl, Abstral, Effentora, Breakyl, Recivit). These six products were never directly compared within one study in cancer pain patients. Physicians currently base their choice of a ROO purely on experience and PK data, which originate mostly from healthy volunteers and are therefore poor indicators of PK profiles in cancer patients.

Study objective

To determine and compare PK profiles of two of the most used ROOs in cancer patients: one intranasal fentanyl formulation (INFC, Instanyl®) and one sublingual fentanyl formulation (SLF, Abstral®).

Study design

Open label, two period crossover study.

Intervention

Patients will take either INFC or SLF at the start of an BTcP episode. Blood samples and VAS scores will be taken before and 5, 10, 15, 20, 30, 45, 60, 90, 120 and 240 minutes after ROO administration. Thereafter, patients will receive the other ROO, either INFC or SLF, during at least three days to titrate to the optimal dose. After this, the second study period starts. After both periods a questionnaire about the patients preference will be conducted.

Study burden and risks

This study brings neither added risks nor benefits directly for the patients. The additional load is 12 blood samples of 2 ml for the determination of PK data, collected with an indwelling venous catheter (Venflon), a VAS before the blood sample collection, and a short questionnaire about the patients* preference.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Patients receiving stable maintenance opioid therapy for chronic cancer pain (as specified in SPCs of tested ROOs)
* Patients suffering from BTcP, according to the Davies 2009 criteria. Both incidental and idiopathic BTcP.
* Patients should have an average of 2 (and maximum of 4) episodes of BTcP per day
* Patients must use one of the formulations used in this study for BTcP, either 100 or 200 µg Instanyl® or 200 or 400 µg Abstral®.
* Patients must be mentally competent and therefore able to sign and date a written informed consent prior to entering the study

Exclusion criteria

Sleep apnea, active brain metastases (with increased intracranial pressure), severe COPD, a recent history of substance abuse
Allergy to one of the constituents of the ROOs Instanyl and Abstral
Mucositis
Participation in another clinical trial in the previous 4 weeks
Use of MAO inhibitors

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Abstral
Generic name:	fentanyl
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Instanyl
Generic name:	fentanyl
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	13-05-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	19-02-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	27-06-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

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
EudraCT	EUCTR2015-000983-32-NL
CCMO	NL50229.098.15