Effects of body mass index (BMI) and smoking on the pharmacokinetics of fentanyl

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28290

Source
Nationaal Trial Register

Health condition

All patients using a stable dose of a fentanyl (Durogesic ®) patch (for at least 8 days).

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Nuts/Ohra

Intervention

Outcome measures

Primary outcome

Main study parameters/endpoints. Pharmacokinetics (clearance, AUC etc)

Secondary outcome

not applicable

Study description

Background summary

SUMMARY

Rationale: Fentanyl is a strong opioïd and is highly lipophilic. Fentanyl pharmacokinetics are characterised by large inter- and inpatient differences, which may have serious consequences for the activity and toxicity profile of this drug. In this study we explore the influence of BMI and smoking behaviour on the pharmacokinetics (i.e. clearance (CL)) of fentanyl.

Objective: Primary objective: To study the relation between BMI and the pharmacokinetics of fentanyl, in patients using a stable dose of the fentanyl patch (Durogesic ®). Secundary objective: to study the relation between smoking and the pharmacokinetics of fentanyl, in patients using a stable dose of the fentanyl patch (Durogesic ®).

Study design: explorative cohort study

Study population: All patients using a stable dose of a fentanyl (Durogesic ®) patch (for at least 8 days).

Intervention (if applicable): not applicable

Main study parameters/endpoints: Pharmacokinetics (Clearance, AUC, etc.)

Study objective

Fentanyl is a strong opioïd and is highly lipophilic. Fentanyl pharmacokinetics are characterised by large inter- and inpatient differences, which may have serious consequences for the activity and toxicity profile of this drug. In this study we explore the influence of BMI and smoking behaviour on the pharmacokinetics (i.e. clearance (CL)) of fentanyl.

Study design

not applicable

Intervention

not applicable

Contacts

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Eligibility criteria

Inclusion criteria

• age > 18 years;

• stable use and dose of fentanyl patch (Durogesic ®) for at least 8 days, irrespective of the dose used;

• written informed consent.

Exclusion criteria

• Using fentanyl as rescue medication (other opioids are allowed)

• Serious psychiatric illness, confusion of intellectual disability

• The use of strong cytochrome P450 inhibitors or inducers.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2014
Enrollment:	80
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

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	NL4496
NTR-old	NTR4672
Other	Erasmus MC : MEC-2013-412

Study results