

Effects of anatomical localization of the fentanyl patch on the pharmacokinetics and pharmacodynamics of fentanyl: A randomised cross-over trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23508

Source

Nationaal Trial Register

Health condition

- cancer patients
- fentanyl patch
- kankerpatienten
- fentanylpleister

Sponsors and support

Primary sponsor: Erasmus Medical Center, Daniel den Hoed Cancer Center

Source(s) of monetary or material Support: NUTS/OHRA

Intervention

Outcome measures

Primary outcome

1 - Effects of anatomical localization of the fentanyl patch on the pharmacokinetic ... 25-05-2025

AUC and clearance.

Secondary outcome

Difference in pain scale.

Study description

Background summary

N/A

Study objective

Fentanyl is highly lipophilic. Localizations with a thicker fatlayer absorb more fentanyl than localizations with a thinner fatlayer. When patients stick the patch in different localizations this can lead to different concentrations of fentanyl. With consequences of underdosing or overdosing the fentanyl.

Study design

1 year.

Intervention

Patients will be asked to stick the fentanyl patch to the upper arm during 9 (3x3) days. Then pharmacokinetic samples will be taken. Afterwards they stick the patch to the ventral thorax and pharmacokinetic samples will be taken. Or vice versa.

Contacts

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Scientific

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Eligibility criteria

Inclusion criteria

1. Stable use of fentanyl patch;
2. 18 years or older;
3. Written informed consent;
4. Stable comedication.

Exclusion criteria

1. Fentanyl rescue medication;
2. Mentally disabled or suffering from a psychiatric disease.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	10-10-2012

Enrollment: 14
Type: Actual

Ethics review

Positive opinion
Date: 08-10-2012
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	NL3507
NTR-old	NTR3654
Other	METC / EudraCTnumber : 2012-193 / 2012-000999-41;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A