SURF studie

No registrations found.

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

Summary

ID

NL-OMON23681

Source
Nationaal Trial Register

Brief title
The SURF study

Health condition

Healthy volunteers
Characteristics of oxycodone and tapentadol.

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Leiden University Medical Center

Intervention

Outcome measures

Primary outcome

- Changes in breath-to-breath minute ventilation as measured at iso-hypercapnia;

- Change in nociception using experimental pain models

Secondary outcome

The drug concentration, respiratory and pain end-points will be used for construction of the Utility Functions.

Study description

Background summary

Opioids differ in the characteristics with respect to wanted effect (analgesia) and side effects (eg. respiratory depression). These effects are best viewed concomitantly allowing comparison between opioid. One way of describing these effects simultaneously is by construction of safety or utility function (UF). In this study, we will determine the UF of two commonly used opioids, tapentadol and oxycodone.

Study objective

In the current study, we will construct utility functions of two opioids, tapentadol and oxycodone, to assess the benefit/harm ratio of these drugs. To that end we will perform a PK PD study in healthy volunteers

Study design

Each subject will be treated 4 times, with at least 1 week in between visits. Each visit will last approximately 8 hours with.

Intervention

Subjects will receive oral tapentadol on two separate occasions, once for assessment of the respiratory effects and once for assessment of the anti-nociceptive effects. Subjects will receive oral oxycodone on the other two separate occasions, once for assessment of the respiratory effects and once for assessment of the anti-nociceptive effects.

Contacts

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Eligibility criteria

Inclusion criteria

- Healthy according to medical history, physical examination, vital signs, lab values, and ECG;

- Age 18-38 years;

- Able to give informed consent;

- Body mass index < 30 kg/m2.

- Female subjects on contraceptives.

Exclusion criteria

- Presence of health issues including presence or history of any psychiatric, medical or neurologic disorder that may interfere with the current study (eg. neuropathic pain conditions);

- Presence or a history of illicit drug use or excessive alcohol consumption (>21 units per week),

- Known allergies to study medication.

- A positive drug screen on the day of screening or on any of the study days,

- Participation in another trial in the 3 months before enrolment,

- Use of medication on a regular basis (e.g. pain medication),

- Inability to fast for at least 8 hours prior to study treatment administration,

- Pregnancy or lactation,

- Inability to communicate with the research team

- Elective surgery during the study period.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-12-2018
Enrollment:	24
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-01-2019
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	NL7454
NTR-old	NTR7696
Other	METC Leiden Den Haag Delft : P18.212 LUMC

Study results

Summary results
N/A