SURF studie

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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

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

Samenvatting

ID

NL-OMON23681

Bron
Nationaal Trial Register

Verkorte titel
The SURF study

Aandoening

Healthy volunteers
Characteristics of oxycodone and tapentadol.

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Leiden University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Changes in breath-to-breath minute ventilation as measured at iso-hypercapnia;
- Change in nociception using experimental pain models

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

LUMC, Anesthesiology, P5
Albinusdreef 2
M. Velzen, van
Leiden 2333 ZA
The Netherlands
+31 (0)71 5262301

Wetenschappelijk

LUMC, Anesthesiology, P5

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Leiden 2333 ZA
The Netherlands
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	31-12-2018
Aantal proefpersonen:	24
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	04-01-2019
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	NL7454
NTR-old	NTR7696
Ander register	METC Leiden Den Haag Delft : P18.212 LUMC

Resultaten

Samenvatting resultaten
N/A