Ademhalingsstudie naar de interactie tussen remifentanil en propofol in gezonde vrijwilligers.

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A mathematically correct PK-PD model will be developed that describes the depressant effect of propofol on breathing with and without a background of remifentanil.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON19898

Bron
NTR

Verkorte titel
PROP-study

Aandoening

Breathing
BIS
Healthy volunteers
Remifentanil
Propofol
Ademhaling
Gezonde vrijwilligers
PK-PD

Ondersteuning

Primaire sponsor: Leiden University Medical Centre
Overige ondersteuning: Self-financing

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Ventilation (l/min);
2. EEG monitoring via BIS;
3. Bloodsampling for propofol concentrations.

Toelichting onderzoek

Achtergrond van het onderzoek

A study aimed at PK-PD modelling of the respiratory effects of propofol in healthy volunteers in different plasma target concentrations, with and without a background infusion of remifentanil.

Doel van het onderzoek

A mathematically correct PK-PD model will be developed that describes the depressant effect of propofol on breathing with and without a background of remifentanil.

Onderzoeksopzet

First run:

30 minutes infusion of 3 three steps of 10 minutes in different Plasma Target Concentrations (0.7, 1.4, 2,1 ng/ml). Heartrate, saturation, EEG/BIS will be measured continously. Bloodsampling will be performed at baseline, 2 minutes after a step change, 5 minutes after a stepchange and just prior to a stepchange (app. at 10 minutes). Bloodsampling will be continued at intervals of 10 minutes untill 30 minutes after the end of the infusion.

After a 2 hr break we will perform the second run.
The second run will be identical to the first, except for a steady state background infusion of remifentanil at 0.8 or 1.6 ng/ml.

Onderzoeksproduct en/of interventie

24 volunteers will participate in two experimental runs lasting about 1 hr with a 2 hr washout period in between.
During each experimental run a 30 minutes infusion of propofol (first run) or propofol + a steady state background of remifentanil (second run) will be performed. The propofol infusion

will be divided in three steps (Target Plasma Concentration of 0.7, 1.4 or 2.1 mcg/ml) that will be administrated in a randomized order. All subjects will receive all steps in propofol. The remifentanil infusion will be a steady state infusion of 0.8 ng/ml or 1.6 ng/ml. This will be randomized and each volunteer will receive one of these background infusion levels. After the 30 minutes infusion an additional 30 minutes of data sampling will be performed for the washout period.

We will perform bloodsampling regularly via an arterial line. Furthermore we will measure ventilation and EEG via BISmonitoring.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy volunteers of either sex;

2. Age 18-45 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. BMI > 35;

2. Presence of any medical disease;

3. History of drug or alcohol abuse;

4. Allergy to study medications;

5. Mallampati 3 or greater;

6. For females: Use of contraceptives required.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	18-11-2010
Aantal proefpersonen:	24
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-12-2010
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	NL2519
NTR-old	NTR2637
Ander register	METC LUMC / CCMO : P10.017 / NL31225.058.10 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A