The influence of painkillers on ventilation when combined with alcohol

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

Samenvatting

ID

NL-OMON21263

Bron
Nationaal Trial Register

Verkorte titel
the ‘A & O’ study

Aandoening

Opioid induced respiratory depression

Ondersteuning

Primaire sponsor: Leiden University Medical Centre
Overige ondersteuning: Sponsor/initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

A shift of the Vi-CO2 response curves measured pre-dose, during alcohol clamp, two times after adminstration of oxycodone and comcomitant administration of alcohol and one after

discontinuation of alcohol administration

Toelichting onderzoek

Achtergrond van het onderzoek

A single-blind, crossover, 3-arm trial in healthy volunteers (phase I: 18-35 year, phase II: 65 years or older) to determine the influence of alcohol on opioid induced respiratory depression. Twelve subjects will be included in each phase of the study, who will have 3 experiment days with different ethanol concentrations (BrAC 0.0 g L-1, BrAC 0.5 g L-1, 1.0 g L-1) combined with oral administration of 20 mg oxycodon. The primary outcome is Vi-CO2 respirtory curved, secondary outcome is analgesia and sedation.

Doel van het onderzoek

It is hypothesized that respiratory depression from the opioid oxycodone will increase with concomitant administration of alcohol. Furthermore it is hypothesized that the increase in respiratory depression is not only dependent on the dosage of alcohol but dependent on age group as well.

Onderzoeksopzet

During 5.5h the subjects will be in the research lab, of which 3.5h the ethanol infusion will take place, once 20 mg oxycodon will be administered orally.
Five pain measurements will be done, five Vi-CO2 response curves will be done.

Onderzoeksproduct en/of interventie

Intravenous intervention of ethanol inducing a steady state BrAC-level (0.5 g L-1 or 1.0 g L-1)
Oral administration of Oxycodone 20 mg IRS

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy subjects

a. aged 18-40 years (phase I)

b. aged 65 years or older (phase II)

2. Body Mass Index 18-30 mm/kg2

3. Subject is able to read and understand the written consent form, complete study-related procedures, and communicate with the study staff.

4. Healthy and free of significant abnormal findings as determined by medical history, physical examination and vital signs.

5. Subject is deemed suitable by the Investigator for inclusion in the study

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Current diagnosis or history of psychiatric disease.

2. Elderly volunteers should have no cognitive impairment defined as a Mini Mental State

Examination (MMSE) score: < 28.

3. Current or chronic medical condition requiring the use of medication considered Cytochrome P-450 (CYP2E1, CYP2D6, CYP3A4) inductor or current use of opioid analgesics.

4. Current diagnosis or history of lung disease (i.e. asthma, COPD, tuberculosis,).

5. Exclusion based on medication use is subject to judgment by investigators.

6. Participation in a clinical drug study during the 60 days preceding the initial dosing of this study.

7. Any history of frequent nausea or vomiting regardless of etiology

8. Weekly alcohol intake exceeding the equivalent of 21 units/week or a positive alcohol breath test during check-in

9. Asian ethnicity

10. Pregnancy ascertained by positive urine pregnancy test on dosing day.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-09-2013
Aantal proefpersonen:	24
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-08-2013
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	NL3964
NTR-old	NTR4123
Ander register	NL45363.058.13 : P13.143
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A