The influence of painkillers on ventilation when combined with alcohol

No registrations found.

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

Summary

ID

NL-OMON21263

Source
Nationaal Trial Register

Brief title
the ‘A & O’ study

Health condition

Opioid induced respiratory depression

Sponsors and support

Primary sponsor: Leiden University Medical Centre
Source(s) of monetary or material Support: Sponsor/initiator

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. To assess whether sedation as measured by VAS scale and BIS monitoring is increased in the alcohol conditions compared to the no alcohol condition.

2. To asess whether anagelsia induceed by oxycodone is affected by alcohol.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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

Contacts

Public
Leiden University Medical Center (LUMC),
Department of Anesthesiology,
P.O. Box 9600
Albert Dahan

Albinusdreef 2
Leiden 2300 RC
The Netherlands
+31 (0)71 5262301
Scientific
Leiden University Medical Center (LUMC),
Department of Anesthesiology,
P.O. Box 9600
Albert Dahan
Albinusdreef 2
Leiden 2300 RC
The Netherlands
+31 (0)71 5262301

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2013
Enrollment:	24
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-08-2013
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	NL3964
NTR-old	NTR4123
Other	NL45363.058.13 : P13.143
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A