Respiratory study determing the utility of respiratory stimulants in healty volunteerds.

No registrations found.

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

Summary

ID

NL-OMON28568

Source
Nationaal Trial Register

Brief title
DOXA-101

Health condition

None

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

1. Determine the respiratory response of low and high doses of doxapram in conjunction with a low dose of opioids in healty volunteers;

2. Determine the respiratory response of low and high doxapram in conjunction with a low dose of opioids and hypercapnia in healty volunteers.

Secondary outcome

1. Determine the respiratory response of low and high doses of doxapram in conjunction with a high dose of opioids in healty volunteers;

2. Evaluate the tolerability of doxapram in conjunction with a low and high dose of opioids in healty volunteers;

3. Evaluate the PK-PD relationship of the respiratory responses of Doxapram in conjunction with a low and high dose of opioids in healty volunteers.

Study description

Background summary

A study to determine the utility of respiratory stimulants with and without opioid therapy and with hypercapnia or ambient air.

Study objective

Development and validation of a clinical Proof-of-Concept study paradigm for determing the clinical utility of respiratory stimulants over the potential therapeutic dose range in the face of opioid respiratory depression and presences of hypercapnia.

Study design

Part 1:

Ventilatory assessments: Every 30 min;

Blood Sample: 28 samples for Alfentanil, 15 samples for Doxapram;

Subjects sedation scale: Every 30 min;

Heartrate, saturation and CO will be measured continously.

Part 2:

Ventilatory assessments: Every 30 min;

Blood Sample: 17 samples for Doxapram;

Subjects sedation scale: Every 30 min;

Heartrate, saturation and CO will be measured continously.

Intervention

8-16 volunteers will be included in Part 1.

In part 1 they will participate during 4 study days. In 2 study days their EtCO2 will be clamped, in 2 study days there will be ambient air and pain measurements will be performed. All 4 study days they will receive Alfentanil in 2 different doses, 2 days they will receive Doxapram in 2 different doses or a placebo.

In Part 2 6-10 patients will be included depended on the results of part 1. During part 2 the patients will receive two doses of Doxapram without Alfentanil.

Furthermore we will measure cardiac output during both parts.

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

Healty volunteers in the age of 18-45 with a BMI between 18-30 kg/mm2. There has to be no ECG abnormalities, no clinical laboratory abnormalities, no clinically significant disease. All subjects must sign the written informed consent.

Exclusion criteria

History of:
Alcohol abuse, anxiety disorder, psychiatric diseases, drug abuse, smoking,bleeding disorders, medical history. allergic reactions, malignancy, malignant hyperthermia.

Other exclusion criteria is family members or allergic reactions.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-07-2012
Enrollment:	18
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-06-2012
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	NL3302
NTR-old	NTR3500
Other	LUMC / EudraCT : P12.084 / 2012-001849-41;

Study results

Summary results
N/A