Validation study: a newly developed neuropathic pain Heat-Capsaicin-Warmth (HCW) sensitization model.

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Primary:Part I:- to determine the effects of gabapentin and remifentanil on the evoked area of hyperalgesia, area of allodynia, pinprick hyperalgesia and background pain using a newly developed HCW sensitization modelPart II: - to determine...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Observational invasive

Summary

ID

NL-OMON34072

Source
ToetsingOnline

Brief title
Gabapentin and remifentanil HCW pain study

Condition

- Peripheral neuropathies

Synonym
Nerve pain, sensitivity to pain stimuli

Research involving
Human

Sponsors and support

Primary sponsor: Top Institue Pharma
Source(s) of monetary or material Support: Ministerie van OC&W,0

Intervention

Keyword: Gabapentin, Neuropathic pain, Remifentanil, Validation

Outcome measures

Primary outcome

Pharmacodynamics:

Size of the area of secondary hyperalgesia and tactile allodynia (von Frey and

brush, respectively); VAS pain intensity sec and upon pinprick stimulation.

Safety:

Adverse events.

Secondary outcome

n.a.

Study description

Background summary

The effects of a single oral administration of gabapentin (trade name Neurontin®) and infusion of remifentanil (trade name Ultiva®) will be studied in a newly developed pain model.

Gabapentin is a registered drug for epilepsy and neuropathic pain. The exact mechanism if action is unknown. It's therapeutic action on neuropathic pain is thought to involve binding to certain (calcium) channels in the central nervous system.

Remifentanil is a registered drug that is already being used for many years at hospitals during surgery. Remifentanil is an opioid like drug which is ultra short-acting. You will receive the drug and the placebo by intravenous infusion. The infusion takes about 45 minutes. Since administration of remifentanil in an effective dose very likely unblinds the subject due to side effects, an active placebo infusion will be used, i.e. diazepam.

The above drugs will be administered to test a pain model, at which well tolerated pain stimuli will be administered. As part of the pain model, capsaicin cream will be applied on your skin of your underarm. Capsaicin is a cream which will cause a heath sensation of the skin and induces redness of the skin. Capsaicin cream consists of an extraction from red pepper.

Study objective

Primary:
Part I:
- to determine the effects of gabapentin and remifentanil on the evoked area of hyperalgesia, area of allodynia, pinprick hyperalgesia and background pain using a newly developed HCW sensitization model
Part II:
- to determine reproducibility of the model with a washout of 14 days

Secondary:
Part I:
- to assess the safety and tolerability of the HCW sensitization model
- to assess the safety and tolerability of a single oral dose of gabapentin and remifentanil

Study design

Design:
A randomized, double-blind, placebo-controlled, three-way crossover study with a washout of fourteen days.

Procedures and assessments
Screening:
Familiarization with study procedures, medical history, allergy check for capsaicin and responsiveness test, demographics, in and exclusion criteria, previous and concomitant medication, physical examination and clinical laboratory (clinical chemistry and haematology).

Follow-up:
- adverse events

Observation period:
Part I: three ambulatory visits
Part II: three ambulatory visits

Pharmacodynamic assessments:
Measurements of secondary hyperalgesia by von Frey filament (64 mN rounded tip), measurements of tactile allodynia by standardized brush, hyperalgesia by pinprick and monitoring of background pain using visual analog scale (VAS)

scores and Bond and Lader VAS; mechanical (pain) detection thresholds post-gabapentin/placebo dose in Part I.

Safety assessments:
AEs throughout study; continuous monitoring of oxygen saturation, heart rate and rhythm, blood pressure and respiratory rate from 55 minutes pre-dose until 40 minutes post end infusion.

Study burden and risks

Procedures: pain, light bleeding, heamatoma, possibly an infection.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy male volunteers, age between 18 and 40 years, caucasian race, BMI between 18 and 27 kg/m2, non or moderate smoker (<10 per day), at screening state of health must satisfy the entry requirements.

Exclusion criteria

Scar tissue on the anterior side of the dominant forearm, mental handicap, actual pain, history of serious allergies or allergic to gabapentin, remifentanil or capsaicin, regular/routine treatment with non-topical medications within 30 days prior to drug administration.

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-06-2010
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Capsaicin
Generic name:	Capsaicin
Registration:	Yes - NL outside intended use

Product type:	Medicine
Brand name:	Neurontin
Generic name:	Neurontin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Ultiva
Generic name:	Ultiva
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	03-06-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-06-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-06-2010
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-07-2010
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
EudraCT	EUCTR2010-020799-53-NL
Other	n.a.
CCMO	NL32621.056.10