VALIDATION STUDY: NOCICEPTIVE PAIN MODEL AND PHARMACOLOGICAL INTERVENTION

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The aim of the present study is to demonstrate that the nociceptive pain model can be used in the clinic of PRA International-Early Development Services (PRA-EDS) for showing the effect of the analgesic remifentanil and therefore for testing the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32823

Source
ToetsingOnline

Brief title
NOCICEPTIVE PAIN MODEL VALIDATION STUDY

Condition

- Other condition

Synonym
acute pain

Health condition

acute pijn

Research involving
Human

Sponsors and support

Primary sponsor: PRA International EDS
Source(s) of monetary or material Support: industrie

Intervention

Keyword: nociceptive, pain model, remifentanil

Outcome measures

Primary outcome

heat detection threshold (HDT), heat pain detection threshold (HPDT), heat pain, cold detection threshold (CDT), cold pain detection threshold (CPDT), cold pain, cold pressor pain, mechanical pain threshold (MPT) and pressure pain threshold (PPT) ; VAS pain intensity during heat pain, cold pain and cold pressor pain

Secondary outcome

AEs, oxygen saturation, heart rate and rhythm, blood pressure and respiratory rate

Study description

Background summary

Pain is divided into 2 main categories: acute and chronic pain. Acute or nociceptive pain is part of a rapid warning relay instructing the motor neurons of the central nervous system to minimize detected physical harm. Chronic pain encompasses neuropathic pain, pain as a direct consequence of a lesion or dysfunction affecting the somatosensory system.

In early clinical development, pain models, including different pain tests, in healthy volunteers can play an important role in the study of pain mechanisms and in the testing of new analgesic drugs. The pain tests provide a useful tool for obtaining an early insight into the analgesic potential. In addition, the pain tests may provide information on dose selection for later phase studies

and on the time course of the analgesia.

Pain detection threshold tests attempt to identify the point at which a painful experience becomes distinguishable from a non-painful one by using a stimulus of increasing intensity. Pain detection thresholds have been found to be sensitive to a number of different analgesic compounds and are a fast and reliable indicator of sensory changes.1,2,3,4 Besides, they are useful in determining the effect of analgesics on the perception of painful stimuli over a period of time in the same subject. In addition, a visual analog scale (VAS) consisting of a vertical bar on a screen anchored with the descriptors *no pain* (numeric value = 0) and *worst possible pain* (numeric value = 100) is often used for the detection of pain.

Study objective

The aim of the present study is to demonstrate that the nociceptive pain model can be used in the clinic of PRA International-Early Development Services (PRA-EDS) for showing the effect of the analgesic remifentanil and therefore for testing the effect of novel analgesic compounds in the future.

Study design

Randomized, double-blind, placebo-controlled, two-way crossover study with a washout of at least 7 days

Intervention

Ultiva (remifentanil) and inducing light pain sensations

Study burden and risks

Ultiva (remifentanil): nausea, vomiting, low blood pressure, slow heart rate, high blood pressure after surgery, itch, muscle rigidity, low respiratory frequency, respiratory disturbances, shivering after surgery.

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

18-40 years of age
BMI 18-30

Exclusion criteria

Evidence of clinically relevant pathology in the history

Study design

Design

Study type:	Interventional
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):	08-12-2008
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ultiva
Generic name:	remifentanil
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	11-11-2008
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	22-11-2008
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	27-11-2008
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	EUCTR2008-007106-11-NL
CCMO	NL25760.056.08