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Pharmacological modulation of heterosynaptic LOng-TErm POtentiation in humans by ONdansetron and DExtromethorphan

Submission date	Recruitment status	[ ] Prospectively registered
03/11/2006	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
04/01/2007	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
04/01/2007	Signs and Symptoms	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Tr 236/16-2/LTP-Ondan-Dex

Study information

Scientific Title

Acronym
LOTEPODEON (LOng-TErm POtentiation DExtromethorphan ONdansetron)

Study objectives
Long-Term Potentiation (LTP) within the nociceptive system is one of the mechanisms underlying central sensitisation, which accounts for some hyperalgesic pain states in chronic pain patients. In the study we will use a human surrogate model of nociceptive LTP to study the involvement of NMDA-receptors and 5-HT3-receptors in the induction of hyperalgesia following high-frequency electrical stimulation of nociceptive afferents in the skin.

We will study the contribution of NMDA- and 5-HT3 receptors in plastic changes within the nociceptive system, which occur typically after a tissue injury, but in contrast to a real lesion we mimic an injury by high-frequency electrical stimulation of nociceptive afferents in the skin. This conditioning stimulation will lead to pain to light tactile stimuli (dynamic mechanical allodynia) and to an increase of pain to punctuate mechanical pain stimuli (static mechanical hyperalgesia). Both phenomena can typically been found in a subset of neuropathic pain patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the local ethics committee (Ethikkommission der Landesärztekammer Rheinland-Pfalz; 15th March, 2003, reference number: 837.002.03(3664)) and was conducted in accordance with the declaration of Helsinki, the German Medicines Act (AMG), and the guidelines of the International Conference on Harmonisation (ICH) for Good Clinical Practice (GCP).

Study design
The trial was designed as a double blind, randomised and placebo-controlled three-way cross-over study (Placebo-Dextromethrophan-Ondansetron).

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Hyperalgesic pain states in chronic pain patients

Interventions
The effect of 150 mg dextromethorphan and 16 mg ondansetron orally (p.o.) will be compared to placebo in a three-way cross-over design. Sensory changes will be determined by Quantitative Sensory Testing (QST) using non-nociceptive and low-intensity painful mechanical and electrical stimuli.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Dextromethrophan and Ondansetron

Primary outcome measure
1. Spread of the area of dynamic allodynia and static hyperalgesia
2. Combined analgesic and anti-hyperalgesic effect to mechancial and electrical stimuli on the site of conditioning stimulation

Secondary outcome measures
1. Anti-hyperalgesic effect to electrical and mechanical test stimuli
2. Analgesic effect to electrical and mechanical test stimuli
3. Anti-wind up

Overall study start date
01/07/2005

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Healthy volunteers of full age
2. Subject familiarised with the experimental procedure prior to experimentation and had given written informed consent
3. At least a 50% increase of pain to pinprick stimuli and a 25% increase of pain to electrical stimuli following high-frequency electrical stimulation in a screening visit

Participant type(s)
Healthy volunteer

Age group
Adult

Sex

Not Specified

Target number of participants
18

Key exclusion criteria
1. Skin lesions at the test and/or control site
2. Use of any medication within one day prior to study onset except contraceptives
3. Known hypersensitivity to histamine or to dextromethorphan and ondansetron and their derivates
4. Any history of allergy or drug hypersensitivity
5. Chronic use of analgesics or Central Nervous System (CNS) active drugs
6. Pregnancy or nursing
7. Any acute or chronic disease

Date of first enrolment
01/07/2005

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Germany

Study participating centre
Institute of Physiology and Pathophysiology
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Sponsor information

Organisation
Individual Sponsor (Germany)

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Sponsor type
Other

Funder(s)

Funder type
Research organisation

Funder Name
The study is supported by a grant from the German Research Foundation (Deutsche Forschungsgemeinschaft) (Germany) (Grant: Tr236/16-2)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration