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Effect of flupirtine on experimental hyperalgesia in humans

Submission date 16/09/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 08/12/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 08/12/2010	**Condition category** Signs and Symptoms	[_] Individual participant data [_] 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
FLUCAP/KAD 162

Study information

Scientific Title
Effect of flupirtine on experimental hyperalgesia in humans: a double-blind, placebo-controlled crossover trial

Study objectives
Assessment of the effect of flupirtine versus placebo on acute pain (analgesia), secondary hyperalgesia, dynamic mechanical allodynia and wind up (pain summation) in healthy volunteers following intradermal capsaicin injection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethics Commission II, Medical Faculty Mannheim of the University of Heidelberg (Med. Ethikkommission II Medizinische Fakultät Mannheim der Universität Heidelberg) approved on the 31st May 2010 (ref: 2010-010F-MA/monozentrisch)
The trial will be 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
Single centre double blind randomised placebo controlled crossover group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Normal skin sensitivity and experimentally-evoked hyperalgesia

Interventions
The effect of 4 x 400 mg (= 1600 mg) flupirtine retard (Trancolong®) applied over 4 days will be compared to placebo in a two-way cross-over design (placebo-flupirtine). Sensory changes in normal skin will be determined by Quantitative Sensory Testing (QST) using non-nociceptive and low-intensity painful mechanical and thermal stimuli, which were applied in runs alternating

between two skin sites on the forearms (a test site and a control site). In addition, the effect of flupirtine versus placebo on experimental mechanical hyperalgesia, which will be induced by intradermal capsaicin injection (100 µg), will be determined.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Flupirtine (Trancolong®)

Primary outcome measure
Hierarchical approach
1. Combined analgesia and anti-hyperalgesia to pinpricks: pain at conditioned skin site (test site) analysed 0.5 - 1.5 hours after capsaicin injection. If present, then:
1.1. Analgesia to pinpricks: pain to pinpricks in unconditioned skin (control site) normalised to pre-capsaicin
1.2. Anti-hyperalgesia: pain to pinpricks at the test site relative to control site (ratio) normalised to pre-capsaicin

Secondary outcome measures
1. Size reduction of area of secondary hyperalgesia
2. Size reduction of area of dynamic mechanical allodynia
3. Size reduction of the flare area (peripheral flupirtine effect)
4. Analgesia to measures of painful thermal and chemical stimuli in unconditioned skin after drug application (QST profile)
5. Wind-up to painful mechanical stimuli

Overall study start date
01/09/2010

Completion date
28/02/2011

Eligibility

Key inclusion criteria
1. Healthy volunteers, age 18 - 65 years
2. Negative pregnancy test (on day of respective visit, female)
3. Written informed consent
4. Clinical laboratory values within the normal range

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Any history of allergy or drug hypersensitivity
2. Any acute or chronic disease
3. Alcohol or drug abuse
4. Use of any medication within 1 day prior to study onset or, in case of any intake of medication during the last 6 weeks, the wash-out period prior to inclusion was at least less than 5 times the corresponding half-life of the medication taken (incl. dermatological applications; except contraceptives)
5. Dermatological, psychiatric or neurological disorder
6. Blood coagulation disorder
7. Chronic or severe liver disease (hep. encephalopathy, cholestase)
8. Myasthenia gravis
9. Acute or recently resolved tinnitus
10. Use of analgesics or CNS active drugs
11. Participation in any clinical study within 30 days prior to this study
12. Any relevant deviation in clinical or laboratory assessment
13. Known hypersensivity to flupirtine and its derivatives
14. Known hypersensitivity to histamine
15. Skin lesions at the test areas
16. Pregnant or nursing women

Date of first enrolment
01/09/2010

Date of final enrolment
28/02/2011

Locations

Countries of recruitment
Germany

Study participating centre
Department of Neurophysiology,
Mannheim
Germany
68167

Sponsor information

Organisation
University of Heidelberg (Germany)

Sponsor details
(represented by Dr. Marina Frost)
Ruprecht-Karls-Universität Heidelberg
Grabengasse 1
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Sponsor type
University/education

Website
http://www.uni-heidelberg.de/index_e.html

ROR
https://ror.org/038t36y30

Funder(s)

Funder type
Industry

Funder Name
Dr. Kade Pharmazeutische Fabrik GmbH (Germany) (FLUCAP/KAD162)

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