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Effect of Premedication on Pain Perception: functional Magnetic Resonance Imaging (fMRI) study of healthy volunteers

Submission date 28/11/2009	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 19/02/2010	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 12/04/2011	**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
2008-006826-33

Study information

Scientific Title
A double blind randomised prospective study on the effect of premedication on pain perception: functional magnetic resonance imaging (fMRI) study of healthy volunteers

Acronym
PPPMRI

Study objectives
Premedication reduces pain-related cerebral activation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local medical ethics committee (Comité de protection des personnes Ouest II) approved on the 13th March 2009 (ref: 2008-36)

Study design
Double blind randomised prospective study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Pain perception

Interventions
Placebo, hydoxyzine or midazolam ingestion one hour before sequential electrical right forearm pain stimulation and fMRI examination.

The interventions consist of a unique dose ingestion of placebo, hydroxyzine (0.9 mg/kg), and midazolam (0.1 mg/kg) in orange juice, in a randomised design with one week between each session. The follow-up is 6 hours in each arm.

Intervention Type

Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hydoxyzine, midazolam

Primary outcome measure
Volume of central pain matrix activation on fMRI, obtained by contrasting painful stimulation period with resting state period during fMRI recording.

Secondary outcome measures
Visual analogic pain score, measured at the end of each 6 seconds painful stimulation period.

Overall study start date
01/12/2009

Completion date
01/12/2010

Eligibility

Key inclusion criteria
1. Informed consent
2. Right handed
3. American Society of Anaesthesiology (ASA) classification I or II
4. No chronic drug therapy
5. No MRI contraindication
6. Accept the interdiction to drive car and drink alcohol until next morning
7. Aged 25 - 65 years, either sex

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
17

Key exclusion criteria
1. Myasthenia
2. Hypersensibility to midazolam and hydroxyzine
3. MRI contraindication

Date of first enrolment

01/12/2009

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
France

Study participating centre
CHU Angers réanimation chirurgicale B
Angers
France
49993 CEDEX 9

Sponsor information

Organisation
University Hospital Centre of Angers (Centre Hospitalier Universitaire d'Angers) (France)

Sponsor details
Direction des affaires médicales et de la recherche
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Sponsor type
Hospital/treatment centre

Website
http://www.chu-angers.fr/

ROR
https://ror.org/0250ngj72

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Centre of Angers (Centre Hospitalier Universitaire d'Angers) (France)

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