

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	<input type="checkbox"/> Prospectively registered
Registration date 19/02/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/04/2011	Condition category Signs and Symptoms	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

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

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Pain perception

Interventions

Placebo, hydroxyzine 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)

Hydroxyzine, midazolam

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Myasthenia
2. Hypersensitivity 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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration