ISRCTN08745124 https://doi.org/10.1186/ISRCTN08745124

# Assessment of single-dose benzodiazepines on insulin secretion, insulin sensitivity and glucose effectiveness in healthy volunteers: a double-blind, placebo-controlled, randomised cross-over trial

| Submission date | Recruitment status |
|---|---|
| 19/12/2003 | No longer recruiting |
| **Registration date** | **Overall study status** |
| 22/12/2003 | Completed |
| **Last Edited** | **Condition category** |
| 29/08/2007 | Nutritional, Metabolic, Endocrine |

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Pierre Petit

**Contact details**
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
UF 7546

# Study information

**Scientific Title**

**Study objectives**
Not provided at time of registration

**Ethics approval required**
Old ethics approval format

**Ethics approval(s)**
Not provided at time of registration

**Study design**
Randomised controlled trial

**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**
Beta-cell function, insulin sensitivity and glucose effectiveness

**Interventions**
Single infusion of diazepam (10 mg), clonazepam (1 mg) or placebo just before a frequently sampled intravenous glucose tolerance test.

**Intervention Type**
Drug

**Phase**
Not Specified

**Drug/device/biological/vaccine name(s)**
Diazepam, clonazepam

**Primary outcome measure**
Not provided at time of registration

**Secondary outcome measures**
Not provided at time of registration

**Overall study start date**
01/01/2002

**Completion date**
01/01/2003

# Eligibility

**Key inclusion criteria**
Healthy male volunteers aged 20-29 years

**Participant type(s)**
Patient

**Age group**
Not Specified

**Sex**
Not Specified

**Target number of participants**
15

**Key exclusion criteria**
Not provided at time of registration

**Date of first enrolment**
01/01/2002

**Date of final enrolment**
01/01/2003

# Locations

**Countries of recruitment**
France

**Study participating centre**
**Centre d'Investigation Clinique - Hôpital Saint Eloi**
Montpellier
France
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# Sponsor information

### Organisation
University Teaching Hospital of Montpellier (CHU de Montpellier) (France)

### Sponsor details
Direction Recherche et Valorisation - Hôpital La Colombière
39 avenue Charles Flahault
Montpellier
France
34295 cedex 5

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/00mthsf17

# Funder(s)

### Funder type
Government

### Funder Name
French Health Products Safety Agency (Agence française de sécurité sanitaire des produits de santé [Afssaps]) (France) - Appel d'offres 1996 de projets de recherche en pharmacologie clinique et thérapeutique

# 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

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | Results | 04/03/2004 | | Yes | No |