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
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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
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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