

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

19/12/2003

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

22/12/2003

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

29/08/2007

Condition category

Nutritional, Metabolic, Endocrine

☐ 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

Centre d'Investigation Clinique - Hôpital Saint Eloi
80 avenue Augustin Fliche
Montpellier
France
34295 cedex 5

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date

01/01/2003

Eligibility

Key inclusion criteria

Healthy male volunteers aged 20-29 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

34295 cedex 5

Sponsor information**Organisation**

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

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

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