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Positron emission tomography (PET) measurement of the displaceability of [11C]FLB 457 from extra-striatal dopamine D2 receptors in man

Submission date	Recruitment status	[_] Prospectively registered
30/09/2004	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
30/09/2004	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
01/12/2010	Other	

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
N0016131985

Study information

Scientific Title

Study objectives
1. To measure binding of [11C]FLB 457 after the administration of methylphenidate and placebo in normal volunteers.
2. To determine if [11C]FLB 457 is displaceable in extra-striatal regions of the brain.

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)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Not Applicable: Metabolism

Interventions
Double-blind, placebo controlled, randomised study to measure binding of [11C]FLB 457 after the administration of methylphenidate and placebo in normal volunteers.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
methylphenidate

Primary outcome measure
To measure accurately extra-striatal dopamine D2 receptor density in man. If [11C]FLB 457 is displaceable from extrastriatal D2 receptors, it will have great potential value for the measurement of extrastriatal dopamine levels.

Secondary outcome measures
Not provided at time of registration

Overall study start date
02/09/2001

Completion date
03/09/2005

Eligibility

Key inclusion criteria
Volunteers: 16. Males 25-65 yrs, females 45-65 yrs.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
16

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
02/09/2001

Date of final enrolment
03/09/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
c/o Lindsay Green, Assistant Direct
London
United Kingdom
W12 0HS

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Hammersmith Hospital NHS Trust

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	01/02/2007		Yes	No