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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Not Specified

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(s)
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.

Key secondary outcome(s))
Not provided at time of registration

Completion date

03/09/2005

Eligibility

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

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
02/09/2001

Date of final enrolment
03/09/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
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London
United Kingdom
W12 0HS

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Hammersmith Hospital NHS Trust

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	01/02/2007		Yes	No