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Investigation of the sensitivity of hypothalmic dopamine receptors using amisulpiride in healthy young men

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/04/2015	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr MJ Kendall

Contact details
Clinical Investigation Unit
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0265115735

Study information

Scientific Title
Investigation of the sensitivity of hypothalmic dopamine receptors using amisulpiride in healthy young men

Study objectives
Does the hormonal response to the dopamine receptor antagonist amisulpiride provide a reliable means of measuring central dopamine receptor sensitivity?

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
Mental and Behavioural Disorders: Psychosis

Interventions
20 Healthy male subjects will be recruited. After undergoing a general health screen, and having had the study explained to them and given informed consent, subjects will be asked to complete the following visit to the laboratory three times in a randomised schedule balanced for order. The first 10 volunteers will be allocated to group 1 to identify the appropriate amisulpiride dose to produce a robust endocrine response. A second separate group of 10 volunteers (group 2) will undergo a repeated test with the amisulpiride dose identified from group 1. Each group will complete the following visits, which will be separated by a minimum period of 10 days.

Group 1: i. Placebo, ii. 200 mg, iii. 400 mg amisulpiride (orally) - to assess dose response

Group 2: i. Placebo, ii. & iii. 2 QO/400 mg amisulpiride (orally), dependent upon the results of group 1 on two separate occasions - to assess repeatability

Neuroendocrine challenge (amisulpiride)
Pharmacological challenge 02 receptor sensitivity. Subject will be cannulated and baseline blood samples (3 ml) taken every 15 min for 30 min before oral administration of amisulpiride or placebo. Blood samples will then be obtained every 15 min for 3.5 h. Approximately 55 ml of blood will be collected during this visit.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
19/12/2002

Completion date
19/04/2003

Eligibility

Key inclusion criteria
A total of 20 male subjects aged 18-30, will be recruited from the population of the University. All subjects will be healthy non-smokers. Posters advertising the study will be displayed around the University of Birmingham and individuals expressing an interest in the study will be given a subject information sheet and have the study explained to them by one of the investigators. Suitable subjects wishing to participate in the study will complete a general health questionnaire and sign a consent form. It will be made clear that subjects are free to withdraw from the study at any time.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
30 Years

Sex
Male

Target number of participants
20

Key exclusion criteria
1. Volunteer suffers from cardiovascular disease
2. Volunteer has/is suffering from an infection or is on medication
3. Volunteer has asthma
4. Volunteer has epilepsy or a predisposing condition
5. Volunteer has a history of kidney disease
6. Volunteer has a history of Parkinson's disease

In addition to the health questionnaire, volunteers will undergo an independent medical screening with Professor MJ Kendall before entering the study to ensure that there are no underlying general health problems or psychological reasons that contraindicates a neuroendocrine challenge with amisulpiride.

Date of first enrolment
19/12/2002

Date of final enrolment
19/04/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
Department of Health (UK)

Sponsor details

Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

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