

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

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

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United Kingdom
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Additional identifiers

Protocol serial number

N0265115735

Study information

Scientific Title

Investigation of the sensitivity of hypothalamic 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

Study type(s)

Not Specified

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 D2 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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

30 years

Sex

Male

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

United Kingdom

England

Study participating centre

University of Birmingham

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

University Hospital Birmingham NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration