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Neural correlates of response to COGnitive behaviour therapy in SCHIZophrenia: a functional magnetic resonance imaging investigation

Submission date 22/07/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [X] Results [ ] Individual participant data
Registration date 22/07/2005	**Overall study status** Completed	
Last Edited 01/11/2012	**Condition category** Mental and Behavioural Disorders	

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
067427

Study information

Scientific Title

Acronym
COGSCHIZ

Study objectives
1. Does successful treatment of symptoms of schizophrenia produce measurable changes at the brain level?
2. Are there brain predictors of the clinical response to cognitive behaviour therapy in schizophrenia?

Please note that as of 19/01/2007 the anticipated end date of this trial has now been shortened to 30/03/2007. The initial anticipated end date of your trial was 30/06/2007.

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Schizophrenia

Interventions

Functional Magnetic Resonance Imaging (MRI) will be applied to investigate brain functions of 60 patients with schizophrenia, 30 of whom will undergo cognitive behaviour therapy. All patients will be scanned twice, 8 to 9 months apart, during a series of tasks known or likely to be sensitive to symptoms of schizophrenia.

Control data will also be obtained from 20 patients with schizophrenia who have shown a good response to their antipsychotic medication and 20 healthy subjects.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Blood-oxygenation-level-dependent response in cortical and sub-cortical regions
2. Symptom scores

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/11/2002

Completion date
30/03/2007

Eligibility

Key inclusion criteria
Patients with a diagnosis of schizophrenia:
1. Who have shown partial or complete resistance to typical or atypical drug therapy
2. Are right handed
3. Have no history of neurological conditions or head injury
4. Can tolerate scanning
5. Can provide written consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
100

Key exclusion criteria

Evidence of primary drug or alcohol abuse or consumption of alcohol or street drugs within 24 hours of scheduled testing.

Date of first enrolment
01/11/2002

Date of final enrolment
30/03/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London (UK)

Sponsor details
c/o Dr Gill Dale
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Sponsor type
University/education

Website
http://www.iop.kcl.ac.uk

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 067427)

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	01/08/2011		Yes	No