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An international study of improving treatment for the most severely ill with schizophrenia

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	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/11/2009	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
NCT00272584

Secondary identifying numbers
N0544099315

Study information

Scientific Title

Study objectives
Background: Clozapine represents a significant advance in the treatment of the most severely ill patients with schizophrenia. However, a subgroup continues to be psychotic and disabled even with adequate clozapine treatment. A trial of risperidone augmentation of clozapine is proposed. This strategy is based on the rationale that risperidone has some documented efficacy as monotherapy in severely ill patients, and may have a somewhat different profile of effects on cognition compared to clozapine.

Hypothesis: Risperidone augmentation will reduce symptoms and improve working memory compared to placebo augmentation.

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
A double-blind, randomised controlled trial of risperidone compared to placebo augmentation will be carried out with 100 subjects. All subjects will continue on clozapine therapy. Symptomatic, functional, side effects and neurocognitive assessments will be carried out at 4, 8 and 26 weeks.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
clozapine, risperidone

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
20/03/2001

Completion date
20/03/2004

Eligibility

Key inclusion criteria
100 Subjects (PROJ 16/10/2000)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
20/03/2001

Date of final enrolment
20/03/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Box No 316
Cambridge
United Kingdom
CB1 5EY

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
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SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Other

Funder Name
Cambridge Consortium - Addenbrookes (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/02/2006		Yes	No