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

ClinicalTrials.gov (NCT)

NCT00272584

Protocol serial number

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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date

20/03/2004

Eligibility

Key inclusion criteria

100 Subjects (PROJ 16/10/2000)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Box No 316

Cambridge United Kingdom CB1 5EY

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Other

Funder Name

Cambridge Consortium - Addenbrookes (UK)

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	02/02/2006		Yes	No