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Cost utility of the latest antipsychotics in severe schizophrenia (CUtLASS): a multi-centre, randomised, controlled trial

Submission date
25/04/2003

Recruitment status
No longer recruiting

Registration date
25/04/2003

Overall study status
Completed

Last Edited
08/11/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://web1.iop.kcl.ac.uk/Extras/Cutlass/index.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 96/19/06

Study information

Scientific Title
Cost utility of the latest antipsychotics in severe schizophrenia (CUtLASS): a multi-centre, randomised, controlled trial

Acronym
CUtLASS

Study objectives
Antipsychotic (neuroleptic) drugs remain central to the treatment of the symptoms of schizophrenia. Conventional drugs are effective in 70% of patients but have frequent neurological side effects. The atypical antipsychotics are a new class of drugs with a lower risk of these side effects and, in the case of clozapine, better efficacy. The cost of these new drugs is 20-30 times that of conventional drugs. There are currently no reliable data about their comparative effectiveness and cost-effectiveness in NHS settings in which to guide practice. If their use continues to expand, the annual drugs budget for schizophrenia in England will increase from £32 million to £240 million. A 4-centre, prospective, randomised, controlled trial is proposed, to evaluate the relative effectiveness of the new drugs compared to conventional drugs and to clozapine in a sample of 702 people with schizophrenia who are resistant to or intolerant of usual treatment. The trial will aim to demonstrate important differences in quality of life and other outcomes at 1 year, assess value for money and identify cost-effective management strategies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
A 4-centre, prospective, 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: Schizophrenia and other psychoses

Interventions
Please note that, as of 14 January 2008, the anticipated start and end dates of this trial have been updated from 1 March 1999 and 28 February 2002 to 1 May 1999 and 30 June 2003, respectively.

Interventions:
1. New drugs
2. Conventional drugs

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Quality of life

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/05/1999

Completion date
30/06/2003

Eligibility

Key inclusion criteria
Schizophrenics who are intolerant or resistant to usual treatment

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
227

Key exclusion criteria
1. Substance use or organic illness as the main cause of psychotic symptoms.
2. History of neuroleptic malignant syndrome (NMS)

Date of first enrolment
01/05/1999

Date of final enrolment
30/06/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Psychiatry
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
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LS2 7UE
+44 (0)1132 545 843
Sheila.Greener@doh.gsi.gov.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	HTA monograph	01/05/2006		Yes	No