

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	<input type="checkbox"/> Prospectively registered
Registration date 25/04/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/11/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Contact name

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Contact details

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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

Quarry Hill

Leeds

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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