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The effect of electroconvulsive therapy (ECT) following propofol and etomidate anaesthesia: a randomised double blind trial.

Submission date 30/09/2004	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2004	**Overall study status** Stopped	
Last Edited 13/04/2011	**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

N0283136357

Study information

Scientific Title

Study objectives
1. To investigate whether an increased stimulus dose is required to produce a tonic/clonic convulsion duration of greater than or equal to 15 s when propofol is used as an alternative to etomidate for anaesthesia during electroconvulsive therapy (ECT).
2. To investigate whether the incidence of cognitive side-effects is influenced independently by the anaesthetic agents propofol and etomidate, or as a consequence of differences in stimulus dose required for ECT. (Cognitive side effects to be measured by Folstein Mini-Mental State Examination [FMM], Paired Associate Learning Test [PALT], and subjective rating of memory).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double blind 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: Electroconvulsive therapy (ECT)

Interventions
1. Etomidate (smallest amount of induction agent to achieve loss of consciousness)
2. Propofol (smallest amount of induction agent to achieve loss of consciousness)

Added 21 July 2008: the trial was discontinued in 2006 due to poor recruitment.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
propofol and etomidate

Primary outcome measure
Evaluation of depression by Beck Depression Inventory and Clinician's Global Impression of Change, number of ECT sessions, duration of motor and EEG seizure, evaluation of cognitive side effects by Folstein Mini-Mental State Examination, Paired Associate Learning Test and subjective rating of memory.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2003

Completion date
01/01/2006

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
Patients, over 18 years old, with a major depressive illness who are to receive electroconvulsive therapy (ECT), and who have given written informed consent for the study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2003

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Worthing & Southlands Hospitals NHS Trust
Worthing
United Kingdom
BN11 2DH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Sussex NHS Research Consortium (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	01/09/2006		Yes	No