ISRCTN86210347 https://doi.org/10.1186/ISRCTN86210347

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

| | | |
|---|---|---|
| **Submission date**<br>30/09/2004 | **Recruitment status**<br>Stopped | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>30/09/2004 | **Overall study status**<br>Stopped | |
| **Last Edited**<br>13/04/2011 | **Condition category**<br>Mental and Behavioural Disorders | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Richard Venn

**Contact details**
Worthing & Southlands Hospitals NHS Trust
Worthing Hospital
Lyndhurst Road
Worthing
United Kingdom
BN11 2DH
+44 (0)1903 205111 x 5151
richard.venn@wash.nhs.uk

## 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 |