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Randomised comparison of bifrontal and unilateral ultrabrief pulse electroconvulsive therapy in major depression

Submission date
11/04/2008

Recruitment status
No longer recruiting

Registration date
09/05/2008

Overall study status
Completed

Last Edited
30/06/2009

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://www.kuleuven.be/onderzoek/onderzoeksdatabank/project/3M05/3M050570.htm

Contact information

Type(s)
Scientific

Contact name
Dr Pascal Sienaert

Contact details
Leuvensesteenweg 517
Kortenberg
Belgium
3070
pascal.sienaert@uc-kortenberg.be

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

3M050570

Study information

Scientific Title

Acronym
BFRUL

Study objectives
1. Ultrabrief bifrontal electroconvulsive therapy (ECT) is as effective as ultrabrief unilateral ECT
2. Ultrabrief bifrontal ECT produces less cognitive side-effects than ultrabrief unilateral ECT

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Catholic University of Leuven. Date of approval: 11/09/2003 (ref: ML2393)

Study design
Randomised controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Depressive disorder/ bipolar disorder

Interventions
Ultrabrief bifrontal ECT vs ultrabrief unilateral ECT. Patients were treated twice weekly until remission and had a mean number of treatment sessions of 11.

Ultrabrief pulse ECT = pulse width of 0.3 msec.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The following were performed at baseline and once every week until response/remission, and 1 and 6 weeks after finishing the course, by a blinded rater:
1. Hamilton Depression Rating Scale (HDRS)
2. Beck Depression Inventory (BDI)
3. Clinical Global Impression (CGI)
4. Patient Global Impression (PGI)

Secondary outcome measures
The following were assessed at baseline and 1 and 6 weeks after finishing the course:
1. Mini Mental State Examination (MMSE)
2. Trail Making Test A&B
3. Continuous Performance Task (CPT)
4. Wisconsin Card Sorting Test (WCST)
5. Rey's Auditory Verbal Learning Test (RAVLT)
6. Letter Number Sequencing (WAIS)
7. Autobiographical Memory Test (AMT)
8. Autobiographical Memory Interview (AMI)
9. Squire Subjective Memory Questionnaire (SSMQ)

Overall study start date
01/10/2003

Completion date
01/10/2007

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Patients with Diagnostic and Statistical Manual of mental disorders fourth edition (DSM-IV)-defined major depressive disorder, either bipolar or unipolar, with or without psychotic symptoms
3. Those who were referred for ECT
4. Those who had a minimum baseline score of 18 on the 17-item Hamilton Rating Scale for Depression (HRSD)
5. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Schizophrenia
2. Neurological illness
3. Cognitive disorder
4. Substance abuse or dependence within the previous year
5. ECT within the past 6 months

Date of first enrolment
01/10/2003

Date of final enrolment
01/10/2007

Locations

Countries of recruitment
Belgium

Study participating centre
Leuvensesteenweg 517
Kortenberg
Belgium
3070

Sponsor information

Organisation
Catholic University Leuven (Belgium)

Sponsor details
University Psychiatric Centre
Kortenberg campus
Leuvensesteenweg 517
Kortenberg
Belgium
3070
+32 2 758 05 11
pascal.sienaert@gmail.com

Sponsor type
University/education

Website
http://www.kuleuven.be/english

ROR
https://ror.org/05f950310

Funder(s)

Funder type
University/education

Funder Name
Catholic University Leuven, University Psychiatric Centre (Belgium)

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	01/07/2009		Yes	No
Results article	patient satisfaction results	01/03/2010		Yes	No