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

Submission date	Recruitment status	Prospectively registered		
11/04/2008	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
09/05/2008	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
30/06/2009	Mental and Behavioural Disorders			

# 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

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

# 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