

P01-49 - THE STUDY PROTOCOL OF THE NORWEGIAN RANDOMIZED CONTROLLED TRIAL OF ELECTROCONVULSIVE THERAPY IN TREATMENT RESISTANT DEPRESSION IN BIPOLAR DISORDER

U. Kessler¹, H. Schøyen², A. Vaaler³, K. Ødegaard¹, P. Bergsholm⁴, O.A. Andreassen^{5,6}, U. Malt^{6,7}, G. Morken⁸

¹MoodNet Research Group, Haukeland University Hospital, Bergen, ²MoodNet Research Group, University Hospital Stavanger, Stavanger, ³Haukeland University Hospital, Bergen, ⁴MoodNet Research Group, Psychiatric Clinic Førde, Førde, ⁵Division of Psychiatry, Oslo University Hospital, Ullevål, ⁶Inst of Psychiatry, University of Oslo, ⁷Oslo University Hospital, Rikshospitalet, Oslo, ⁸Østmarka Psychiatric Department, St. Olav University Hospital, Trondheim, Norway

Introduction: The treatment of depressive phases of bipolar disorder is challenging. Electroconvulsive therapy (ECT) is generally considered to be the most effective treatment even if there are no randomized controlled trials (RCT) of ECT in bipolar depression. The safety of ECT is well documented, but there are some controversies as to the cognitive side effects.

Objectives: To compare the effects and side effects of ECT with pharmacological treatment in treatment resistant bipolar depression. Cognitive changes during the treatment will be measured, as well as quality of life.

Method: A prospective, randomised controlled multi-centre trial. 6- week acute treatment trial with 7 clinical assessments. Follow up visit at 26 weeks or until remission (max 52 weeks). A neuropsychological test battery designed to be sensitive to changes in cognitive function will be used.

Setting: Nine study centres across Norway, all acute psychiatric wards

Sample: 132 patients aged 18 and over, who fulfil criteria for treatment resistant depression in bipolar disorder, MADRS score of at least 25 at baseline

Intervention: Intervention group: 3 sessions per week for up to 6 weeks, total up to 18 sessions. Control group: algorithm-based pharmacological treatment as usual.

Results: Six departments have included 43 patients since start in May 2008.

Conclusion: This study is the first randomized controlled trial that aims to investigate whether ECT is better than pharmacological treatment as usual in treatment resistant bipolar depression. Possible long lasting cognitive side effects will be evaluated. The study is investigator initiated, without support from industry.