AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Not applicable
ACTIVE INGREDIENT: Not applicable

Study No: NIS-NES-XXX-2011/1   NCT01360307

Validation of the Spanish version of the Clinically Useful Depression Outcome Scale (CUDOS)

Developmental phase: Not applicable
Study Completion Date: 11/30/2011
Date of Report: 06/20/2012

OBJECTIVES:

To assess the psychometric properties of the Spanish version of the Clinically Useful Depression Outcome Scale (CUDOS) in patients with major depressive disorder.

METHODS:

A non-interventional, cross-sectional psychometric study was conducted in 44 primary care centres. Eligibility criteria included outpatients being at least 18 years old and having a diagnosis of major depressive disorder according to DSM-IV-TR and PRIME-MD criteria in the last three months. Patients participated only if they gave written informed consent. The study was approved by the Galicia´s Institutional Review Board (Santiago de Compostela, Spain).

The Clinically Useful Depression Outcome Scale is a brief, self-administered questionnaire that evaluates depressive symptoms, functioning, and health-related quality of life. The CUDOS consists of 18 questions answered on a 5-point Likert ordinal scale. The total score ranges from 0 to 90 points (higher scores indicating a more severe level of depressive symptoms). The original version was back-translated and a focus group was conducted to improve the comprehension of the items. Patients were evaluated with the

Hamilton Depression Rating scale (HAMD-17), the Clinical Global Impression of Severity (CGI-S), the Patient Global Impression of Severity (PGI-S), the Social Occupational Functioning scale (SOFAS), the SF-36 Health Survey (Physical –PCS- and Mental –MCS- Component Summaries), and the CUDOS.

CUDOS feasibility, internal consistency (Cronbach´s α), convergent validity (Spearman correlation with SOFAS, HAMD-17, and SF-36) and discriminant validity (differences in CUDOS values according to HAMD-17 classification of severity and the CGI-S: Kruskal-Wallis and Mann-Whitney U –Bonferroni correction-) were evaluated. Finally, a cut-off score (Receiver Operation Curve-ROC- analysis) was calculated using the HAMD-17 as criterion (0-7= remission).

RESULTS:

A total of 305 patients were analyzed. The mean age was 51.7 years (SD = 15.5), sixty-nine percent of them were female (N= 212). The mean HAMD-17 and CUDOS scores were 16.7 (SD = 7.3) and 29.8 (SD = 12.1), respectively. The mean SOFAS score was 62.5 (SD = 16.7). According to the HAMD-17, 7.9% of patients were in remission, 29.8% presented mild depression, 22.0% moderate depression, 21.0% severe and 19.3% very severe.

The CUDOS mean completation time was 4.4 minutes (SD = 2.4) and floor or ceiling effects were found in less than 1% of patients. The Cronbach´s α coefficient was high (0.877). Correlations with CUDOS were -0.402 (SOFAS), 0.431 (HAMD-17), -0.224 (PCS), -0.650 (MCS); $p<0.001$. Differences in CUDOS scores between severity levels were found ($p<0.03$; Bonferroni correction). The ability of CUDOS for predicting remission was adequate (AUC= 0.837; CI= 0.740-0.934; $p<0.001$). A cut-off point (CUDOS= 24) was estimated (sensitivity=0.81, specificity= 0.77).