AstraZeneca

Non-Interventional Study (NIS) Report	
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Effectiveness of atypical antipsy chotics on anhedonic features in patients with schizophrenia (PLEASURE study)

NIS REPORT SYNOPSIS

Effectiveness of atypical antipsy chotics on anhedonic features in patients with schizophrenia (PLEASURE study)

Study Site(s)

There were 214 patients at 21 centres in Korea.

Publications

None at the time of writing this report.

Study dates

First Subject In: 10 August 2010

Last Subject Last Visit: 28 July 2011

Medicinal products and concomitant medication

Atypical antipsychotics

Objectives

The objective of the study was to monitor the changes of anhedonic features in patients with schizophrenia, treated with atypicals for 3 months.

Study design

There were no experimental component associated with this study and all observational activities had to be part of routine care visit : baseline(week 0), week4 and week12

Target subject population

Patients have a diagnosis of schizophrenia, as defined by DSM-IV-TR

Study variable(s)

Primary outcome variable:

- The change of total score of SHAPS between baseline and 12 weeks

Secondary outcome variables:

- Changes of Clinical Global Impression (CGI)-Severity score between baseline and the end of treatment
- Proportion of patients having a score of 1 or 2 in CGI-I score at the end of treatment
- Proportion of significantly improved patients in SHAPS total score (more than 30%) from baseline to the end of treatment
- The mean change form baseline in MADRS total score

Statistical methods

Parametric paired t-test to compare primary endpoint changes before and after an observation was used in this study. Otherwise relevant statistics were presented as the measures. The proportion of patients achieving more than 30%improvement in SHAPS from baseline at week 12 and a score of 1 or 2 in CGI-I score at the end of treatment were also evaluated as a secondary endpoint. The change of treatment was assessed by parametric paired t-test.

Analysis of effectiveness endpoints was performed using the intent-to-treat population (ITT) as primary analysis and the per-protocol population (PP) for consistency check. The ITT population consisted of all patients who received at least one dose of study treatment and who had measurement at baseline and at least one on the treatment assessment. PP population defined as all ITT patients with no major protocol violations and/or deviations. If patients discontinue the study prior to week 12, the last-visit observations were carried forward (LOCF).

Subject population

A total of 214 were enrolled for participating in this study.

The demographic is summarized in Table S1. The mean age of ITT set was 40.9years. The total number of male and female of ITT set were 59(38.6%) and 94(61.4%), respectively.

Table S1. Demographic

		Total set N=214	ITT set N=153
Age (years)	Mean[SD]	40.3[11.1]	40.9[11.4]
Sex (male/female)	n (%)	90(42.1)/124(57.9)	59(38.6)/94(61.4)
Diagnosis	N	214	153
1. Paranoid type	n(%)	151(70.6)	112(73.2)
2. Catatonic type	n(%)	1(0.1)	1(0.7)
3. Residual type	n(%)	15(7.0)	12(7.8)
4. Undifferentiated type	n(%)	47(22.0)	28(18.3)
Expected Duration	N	214	153
	Mean[SD]	95.1[86.8]	94.6[84.7]
	Median	61.5	70
	(Min, Max)	(1, 360)	(1, 360)
Psychological disorder except for schizophrenia	N	203	148
Yes	n(%)	2(1.0)	1(0.7)
Comorbid Disorders	N	214	153
Yes	n(%)	13(6.1)	9(5.9)
Family history	N	203	148
Yes	n(%)	2(1.0)	1(0.7)
Father	n(%)	5(31.3)	3(23.1)
Mother	n(%)	3(18.8)	2(15.4)
Brother	n(%)	7(43.8)	7(53.8)
Sister	n(%)	1(43.8)	1(7.7)
Sons and daughters	n(%)	0	0

Summary of results

The following categories based on SHAPS score were presented: In ITT set, The mean total score of SHAPS in Baseline and Week 12 are 7.1 and 4.9, respectively. The change of total score of SHAPS between baseline and 12 weeks is -2.3(95% CI: -3.2, -1.6) in ITT set. And there was statistically significant reduction in SHAPS total score (p-value<.0001) (Table S2).

Table S2. The change of total score of SHAPS between baseline and 12 weeks

Set		Baseline	Week 12	Change	P-value*
ITT set	N=153				
	Mean[SD] (Score)	7.1[4.5]	4.9[4.0]	-2.3[4.5]	<.0001
PP set	N=134				

	Mean[SD] (Score)	7.1[4.6]	4.7[3.9]	-2.4[4.7]	<.0001

* Paired t-test

In ITT set, the changes in CGI-S score between baseline and the end of treatment is -1.0(95% CI: -1.2, -0.8). This result is statistically significant decreases (p-value<.0001).

The mean change from baseline in MADRS total score is -6.3 (95% CI: -7.5, -5.2) in ITT set. The CGI-Severity score and MADRS total score at week 12 was significantly lower than at baseline (p-value<.0001).

The proportion of patients having a score 1 or 2 in CGI-I score at the end of treatment was 35.6% in ITT set. And the proportion of significantly improved patients in SHAPS total score (more than 30%) from baseline to the end of treatment was 73.2% in ITT set (Table S3).

Table S3. Summary of Secondary variables (ITT set)

Secondary variables		Statistics	P-value*
Change in CGI-S	N	118	<.0001
	Mean[SD] (Score)	-1.0[1.0]	
Change in MADRS	N	118	<.0001
	Mean[SD] (Score)	-6.3[6.1]	
Proportion of score of 1 or 2 in CGI-I	N	118	
	n(%)	42(35.6)	
Proportion of significantly improved in SHAPS total score (more than 30%)	N	153	
	n(%)	112(73.2)	

* Paired t-test