ClinicalTrials.gov PRS
Protocol Registration and Results System

ID: 12213A Short-term Study of Combination Treatment of Escitalopram and Gaboxadol in Major Depressive Disorder NCT00807248

Protocol Registration and Results Preview

Close

Short-term Study of Combination Treatment of Escitalopram and Gaboxadol in Major Depressive Disorder

This study has been completed.

Sponsor:	H. Lundbeck A/S
Collaborators:	
Information provided by (Responsible Party):	H. Lundbeck A/S
ClinicalTrials.gov Identifier:	NCT00807248

Purpose

To compare the efficacy of escitalopram fixed dose 20 mg/day in combination with fixed doses of gaboxadol (5 and 10 mg/day) versus escitalopram fixed dose 20 mg/day after 8 weeks of treatment in patients with Major Depressive Disorder

Condition	Intervention	Phase
Major Depressive Disorder	Drug: Escitalopram placebo Drug: Gaboxadol placebo Drug: Escitalopram 20 mg Drug: Gaboxadol 5 mg Drug: Gaboxadol 10 mg	Phase 2

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Investigator), Randomized, Efficacy Study

Official Title: Randomised, Double-Blind, Parallel-Group, Placebo-Controlled, Fixed-Dose Study of Escitalopram in Combination With Two Fixed Doses of Gaboxadol Compared to Escitalopram in Major Depressive Disorder

Further study details as provided by H. Lundbeck A/S:

Primary Outcome Measure:

- Montgomery and Åsberg Depression Rating Scale (MADRS) [Time Frame: Baseline to 8 weeks] [Designated as safety issue: No]
  The MADRS is a 10-item rating scale designed to assess the severity of the symptoms in depressive illness and to be sensitive to treatment effects. Symptoms are rated on a 7-point scale from 0 (no symptom) to 6 (severe symptom). Definitions of severity are provided at 2-point intervals. The total score of the 10 items ranges from 0 to 60.

Secondary Outcome Measures:

- MADRS [Time Frame: From baseline to Week 8] [Designated as safety issue: No]
  The MADRS is a 10-item rating scale designed to assess the severity of the symptoms in depressive illness and to be sensitive to treatment effects. Symptoms are rated on a 7-point scale from 0 (no symptom) to 6 (severe symptom). Definitions of severity are provided at 2-point intervals. The total score of the 10 items ranges from 0 to 60.

- Hospital Anxiety and Depression Scale (HADS) [Time Frame: Mean change from baseline to Week 8] [Designated as safety issue: No]
  The HADS is a patient-rated scale designed to screen for anxiety and depressive states in medical patients. It consists of two sub-scales: the D-scale measures depression and the A-scale measures anxiety. Each sub-scale contains 7 items, and each item is rated from 0 (absent) to 3 (maximum severity). The score of each sub-scale ranges from 0 to 21, and are analysed separately. The total HADS score ranges from 0 to 42.

- Insomnia Severity Index (ISI) [Time Frame: Mean change from baseline to Week 8] [Designated as safety issue: No]
  The ISI is both a brief screening measure of insomnia and an outcomes measure for use in treatment research. It is a brief self-report instrument measuring the patient's perception of his or her insomnia, and it comprises 7 items. Each item is rated on a 0-4 scale and the total score ranges from 0 to 28. 0 = no symptoms and 28 = severe symptoms.

- Sheehan Disability Scale (SDS): Family Subscale [Time Frame: Mean change from baseline to Week 8] [Designated as safety issue: No]
  The SDS comprises self-rated items designed to measure impairment. The patient rates the extent to which his or her (1) work, (2) social life or leisure activities and (3) home life or family responsibilities are impaired on a 10-point visual analogue scales, on which 0 = normal functioning and 10 = severe functional impairment.

- SDS: Work Subscale [Time Frame: Mean change from baseline to Week 8] [Designated as safety issue: No]
  The SDS comprises self-rated items designed to measure impairment. The patient rates the extent to which his or her (1) work, (2) social life or leisure activities and (3) home life or family responsibilities are impaired on a 10-point visual analogue scales, on which 0 = normal functioning and 10 = severe functional impairment.

- SDS: Social Subscale [Time Frame: Mean change from baseline to Week 8] [Designated as safety issue: No]
  The SDS comprises self-rated items designed to measure impairment. The patient rates the extent to which his or her (1) work, (2) social life or leisure activities and (3) home life or family responsibilities are impaired on a 10-point visual analogue scales, on which 0 = normal functioning and 10 = severe functional impairment.

- Clinical Global Impression - Severity of Illness (CGI-S) [Time Frame: Mean change from baseline to Week 8] [Designated as safety issue: No]
  The CGI-S provides the clinician's impression of the patient's current state of mental illness. The clinician uses his or her clinical experience of this patient population to rate the severity of the patient's current mental illness on a 7-point scale ranging from 1 (Normal - not at all ill) to 7 (among the most extremely ill patients).

- Clinical Global Impression - Global Improvement (CGI-I) [Time Frame: at Week 8] [Designated as safety issue: No]
  The CGI-I provides the clinician's impression of the patient's improvement (or worsening). The clinician assesses the patient's condition relative to a baseline on a 7-point scale ranging from 1 (very much improved) to 7 (very much worse).

Enrollment: 490
Study Start Date: November 2008
Study Completion Date: February 2010
Primary Completion Date: December 2009

Arms	Assigned Interventions
Placebo Comparator: Escitalopram placebo and gaboxadol placebo	Drug: Escitalopram placebo Once daily before bedtime for 8 weeks Drug: Gaboxadol placebo Once daily before bedtime for 8 weeks
Active Comparator: Escitalopram 20 mg and gaboxadol placebo	Drug: Gaboxadol placebo Once daily before bedtime for 8 weeks Drug: Escitalopram 20 mg Once daily before bedtime for 8 weeks Other Names: • Escitalopram = Cipralex/Lexapro/Seroplex/Sipralexa
Experimental: Escitalopram 20 mg and gaboxadol 5 mg	Drug: Escitalopram 20 mg Once daily before bedtime for 8 weeks Other Names: • Escitalopram = Cipralex/Lexapro/Seroplex/Sipralexa Drug: Gaboxadol 5 mg Once daily before bedtime for 8 weeks
Experimental: Escitalopram 20 mg and gaboxadol 10 mg	Drug: Escitalopram 20 mg Once daily before bedtime for 8 weeks Other Names: • Escitalopram = Cipralex/Lexapro/Seroplex/Sipralexa Drug: Gaboxadol 10 mg Once daily before bedtime for 8 weeks

Subjects participating in this study will be respectively randomised (1:2:2:2) to receive either:

- placebo or
- escitalopram 20 mg/day or
- escitalopram 20 mg/day in combination with gaboxadol 5 mg/day or
- escitalopram 20 mg/day in combination with gaboxadol 10 mg/day

Eligibility

Ages Eligible for Study: 18 Years to 65 Years
Genders Eligible for Study: Both

Inclusion Criteria:

Clinical Diagnosis of MDD according to DSM-IV-TR criteria:

- With reported duration of the current major depressive episode of at least 3 months
- With MADRS total score of at least 30

Exclusion Criteria:

The patient has 1 or more of the following:

- Any current psychiatric disorder other than MDD as defined in the DSM-IV-TR
- Current or past history of: manic or hypomanic episode, schizophrenia, or any other psychotic disorder, including major depression with psychotic features, mental retardation, organic mental disorders, or mental disorders due to a general medical condition as defined in the DSM-IV-TR
- Any substance disorder (except nicotine and caffeine) within the previous 6 months as defined in the DSM-IV-TR
- Presence or history of a clinically significant neurological disorder (including epilepsy)
- Neurodegenerative disorder (Alzheimer disease, Parkinson disease, multiple sclerosis, Huntington disease, etc)
- Any Axis II disorder that might compromise the study
- Previous use of hallucinogenic drug

The patient has a significant risk of suicide according to the investigator's opinion, or has a score >=5 on item 10 (suicidal thoughts) of the MADRS, or has made a suicide attempt in the previous 12 months.

Contacts and Locations

Locations

Austria

AT001
Vienna, Austria, 1090

Russian Federation

RU019
Barnaul, Russian Federation, 656022

RU018
Ekaterinburg, Russian Federation, 620905

RU029
Izhevsk, Russian Federation, 426054

RU020
Kemerovo, Russian Federation, 650036

RU010
Krasnodar, Russian Federation, 350087

RU012
Krasnodar, Russian Federation, 350007

RU022
Kursk, Russian Federation, 30500

RU007
Moscow, Russian Federation, 144009

RU001
Moscow, Russian Federation, 119992

RU002
Moscow, Russian Federation, 119992

RU003
Moscow, Russian Federation, 127083

RU026
Moscow, Russian Federation, 115522

RU015
Moscow, Russian Federation, 107076

RU028
Moscow, Russian Federation, 119992

RU027
Saransk, Russian Federation, 430030

RU013
Saratov, Russian Federation, 410060

RU024
Saratov, Russian Federation, 410038

RU021
Tomsk, Russian Federation, 634014
RU016
Tver, Russian Federation, 170005
RU014
Volgograd, Russian Federation
RU011
Yaroslavl, Russian Federation, 150003

Investigators

Study Director: Email contact via H. Lundbeck A/S LundbeckClinicalTrials@lundbeck.com

More Information

Results Publications:

Kasper S, Ebert B, Larsen K, Tonnoir B. Combining escitalopram with gaboxadol provides no additional benefit in the treatment of patients with severe major depressive disorder. Int J Neuropsychopharmacol. 2012 Jul;15(6):715-25. doi: 10.1017/S146114571100112X. Epub 2011 Oct 19.

Responsible Party: H. Lundbeck A/S
Study ID Numbers: 12213A
2008-000506-36 [Registry ID: EudraCT]
Health Authority: Austria: Federal Office for Safety in Health Care
Russia: Ministry of Health of the Russian Federation

Study Results

Participant Flow

Recruitment Details	The patients were recruited from specialist inpatient and outpatient clinics.
Pre-Assignment Details	

Arm/Group Title	Placebo (Orally, Once Daily)	Escitalopram 20 mg and Placebo (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)	Total (Not public)
▼ Arm/Group Description	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	
Period Title: **Overall Study**					
Started	71	140	139	140	490
Completed	50	128	121	126	425
Not Completed	21	12	18	14	65
Reason Not Completed					
Adverse Event	1	2	2	6	11
Lack of Efficacy	14	4	8	3	29
Protocol Violation	0	1	1	0	2
Withdrawal of Consent	5	5	5	5	20
Lost to Follow-up	1	0	0	0	1
Other Reason	0	0	2	0	2
(Not Public)	Not Completed = 21 Total from all reasons = 21	Not Completed = 12 Total from all reasons = 12	Not Completed = 18 Total from all reasons = 18	Not Completed = 14 Total from all reasons = 14	

Baseline Characteristics

Arm/Group Title	Placebo (Orally, Once Daily)	Escitalopram 20 mg and Placebo (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)	Total
▼ Arm/Group	[Not specified]	[Not specified]	[Not specified]	[Not specified]	

Description	NOTE : An entry in Arm/Group Description is recommended.	NOTE : An entry in Arm/Group Description is recommended.	NOTE : An entry in Arm/Group Description is recommended.	NOTE : An entry in Arm/Group Description is recommended.	
Overall Number of Baseline Participants	71	140	139	140	**490**
▼ Baseline Analysis Population Description [Not specified]					
Age, Continuous Mean (Standard Deviation) Units: years	42.6 (11.6)	41.6 (12.6)	42.6 (11.8)	41.5 (10.5)	42.0 (11.7)
Gender, Male/Female Measure Type: Number Units: participants					
Female	53	96	96	93	338
Male	18	44	43	47	152
Montgomery and Åsberg Depression Rating Scale (MADRS) [1] Mean (Standard Deviation) Units: Scores on a scale	34.7 (4.2)	35.4 (4.3)	35.3 (3.4)	34.7 (3.8)	35.1 (3.9)
	[1] The MADRS is a 10-item rating scale designed to assess the severity of the symptoms in depressive illness and to be sensitive to treatment effects. Symptoms are rated on a 7-point scale from 0 (no symptom) to 6 (severe symptom). Definitions of severity are provided at 2-point intervals. The total score of the 10 items ranges from 0 to 60.				
Hospital Anxiety and Depression Scale (HADS) [1] Mean (Standard Deviation) Units: Scores on a scale	27.5 (5.9)	28.2 (5.3)	28.1 (5.5)	27.4 (5.5)	27.8 (5.5)
	[1] The HADS is a patient-rated scale designed to screen for anxiety and depressive states in medical patients. It consists of two sub-scales: the D-scale measures depression and the A-scale measures anxiety. Each sub-scale contains 7 items, and each item is rated from 0 (absent) to 3 (maximum severity). The score of each sub-scale ranges from 0 to 21, and are analysed separately. The total HADS score ranges from 0 to 42.				
Insomnia Severity Index (ISI) [1] Mean (Standard Deviation) Units: Scores on a scale	18.4 (5.0)	18.6 (4.7)	18.2 (4.4)	18.1 (4.8)	18.3 (4.7)
	[1] The ISI is both a brief screening measure of insomnia and an outcomes measure for use in treatment research. It is a brief self-report instrument measuring the patient's perception of his or her insomnia, and it comprises 7 items. Each item is rated on a 0-4 scale and the total score ranges from 0 to 28. 0 = no symptoms and 28 = severe symptoms.				
Sheehan Disability Scale (SDS): Family Subscale [1] Mean (Standard Deviation) Units: Scores on a scale	7.0 (1.4)	7.1 (1.6)	7.2 (1.3)	6.9 (1.4)	7.1 (1.4)
	[1] The SDS comprises self-rated items designed to measure impairment. The patient rates the extent to which his or her (1) work, (2) social life or leisure activities and (3) home life or family responsibilities are impaired on a 10-point visual analogue scales, on which 0 = normal functioning and 10 = severe functional impairment.				
SDS: Work Subscale [1] Mean (Standard Deviation) Units: Scores on a scale	7.3 (1.2)	7.4 (1.3)	7.3 (1.5)	7.0 (1.4)	7.2 (1.4)
	[1] The SDS comprises self-rated items designed to measure impairment. The patient rates the extent to which his or her (1) work, (2) social life or leisure activities and (3) home life or family responsibilities are impaired on a 10-point visual analogue scales, on which 0 = normal functioning and 10 = severe functional impairment.				
SDS: Social Subscale [1] Mean (Standard Deviation) Units: Scores on a scale	7.0 (1.4)	7.1 (1.4)	7.1 (1.5)	6.9 (1.6)	7.0 (1.5)
	[1] The SDS comprises self-rated items designed to measure impairment. The patient rates the extent to which his or her (1) work, (2) social life or leisure activities and (3) home life or family responsibilities are impaired on a 10-point visual analogue scales, on which 0 = normal functioning and 10 = severe functional impairment.				
Clinical Global Impression - Severity					

of Illness (CGI-S) [1] Mean (Standard Deviation) Units: Scores on a scale	4.4 (0.9)	4.5 (0.9)	4.3 (0.9)	4.4 (0.9)	4.4 (0.9)
	[1] The CGI-S provides the clinician's impression of the patient's current state of mental illness. The clinician uses his or her clinical experience of this patient population to rate the severity of the patient's current mental illness on a 7-point scale ranging from 1 (Normal - not at all ill) to 7 (among the most extremely ill patients).				

Outcome Measures

1. Primary Outcome

Title:	Montgomery and Åsberg Depression Rating Scale (MADRS)
Description:	The MADRS is a 10-item rating scale designed to assess the severity of the symptoms in depressive illness and to be sensitive to treatment effects. Symptoms are rated on a 7-point scale from 0 (no symptom) to 6 (severe symptom). Definitions of severity are provided at 2-point intervals. The total score of the 10 items ranges from 0 to 60.
Time Frame:	Baseline to 8 weeks
Safety Issue?	No

Outcome Measure Data ✔ 4 Notes

Analysis Population Description

Mean change from baseline to Week 8: Full-analysis Set (FAS), Last Observation Carried Forward (LOCF), Analysis of Covariance (ANCOVA)

Arm/Group Title	Placebo (Orally, Once Daily)	Escitalopram 20 mg and Placebo (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)
Arm/Group Description:	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.
Number of Participants Analyzed	71	139	139	140
Mean (Standard Error) Units: Scores on a scale	-13.4 (1.1)	-19.0 (0.9)	-18.5 (0.9)	-19.4 (0.9)

Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Groups	Escitalopram 20 mg and Placebo (Orally, Once Daily), Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.6405
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.45
	Confidence Interval	(2-Sided) 95% -2.34 to 1.44
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.96

	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✔

Statistical Analysis Overview	Comparison Groups	Escitalopram 20 mg and Placebo (Orally, Once Daily), Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.6227
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.47
	Confidence Interval	(2-Sided) 95% -1.41 to 2.35
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.96
	Estimation Comments	[Not specified]

2. Secondary Outcome

Title:	MADRS
▼ Description:	The MADRS is a 10-item rating scale designed to assess the severity of the symptoms in depressive illness and to be sensitive to treatment effects. Symptoms are rated on a 7-point scale from 0 (no symptom) to 6 (severe symptom). Definitions of severity are provided at 2-point intervals. The total score of the 10 items ranges from 0 to 60.
Time Frame:	From baseline to Week 8
Safety Issue?	No

▼ Outcome Measure Data ✔ 4 Notes

▼ Analysis Population Description

Mean change from baseline to Week 8 (FAS, LOCF, ANCOVA)

Arm/Group Title	Placebo (Orally, Once Daily)	Escitalopram 20 mg and Placebo (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)
▼ Arm/Group Description:	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.
Number of Participants Analyzed	71	139	139	140
Least Squares Mean (Standard Error) Units: Scores on a scale	-13.4 (1.1)	-19.0 (0.9)	-18.5 (0.9)	-19.4 (0.9)

▼ Statistical Analysis 1 ✔

Statistical Analysis	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Placebo (Orally, Once Daily)

Overview	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-5.55
	Confidence Interval	(2-Sided) 95% -7.98 to -3.11
	Parameter Dispersion	Type: Standard Error of the mean Value: 1.24
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✔

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-5.09
	Confidence Interval	(2-Sided) 95% -7.53 to -2.66
	Parameter Dispersion	Type: Standard Error of the mean Value: 1.24
	Estimation Comments	[Not specified]

▼ Statistical Analysis 3 ✔

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of	P-Value	<0.0001

Hypothesis	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-6.00
	Confidence Interval	(2-Sided) 95% -8.43 to -3.56
	Parameter Dispersion	Type: Standard Error of the mean Value: 1.24
	Estimation Comments	[Not specified]

3. Secondary Outcome

Title:	Hospital Anxiety and Depression Scale (HADS)
▼ Description:	The HADS is a patient-rated scale designed to screen for anxiety and depressive states in medical patients. It consists of two sub-scales: the D-scale measures depression and the A-scale measures anxiety. Each sub-scale contains 7 items, and each item is rated from 0 (absent) to 3 (maximum severity). The score of each sub-scale ranges from 0 to 21, and are analysed separately. The total HADS score ranges from 0 to 42.
Time Frame:	Mean change from baseline to Week 8
Safety Issue?	No

▼ Outcome Measure Data ✓ 4 Notes

▼ Analysis Population Description

Mean change from baseline to Week 8 (FAS, LOCF, ANCOVA)

Arm/Group Title	Placebo (Orally, Once Daily)	Escitalopram 20 mg and Placebo (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)
▼ Arm/Group Description:	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.
Number of Participants Analyzed	71	139	139	140
Mean (Standard Error) Units: Scores on a scale	-9.7 (1.0)	-14.7 (0.8)	-14.1 (0.8)	-15.0 (0.7)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Placebo (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)

	Estimated Value	-4.98
	Confidence Interval	(2-Sided) 95% -7.13 to -2.84
	Parameter Dispersion	Type: Standard Error of the mean Value: 1.09
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✔

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-4.46
	Confidence Interval	(2-Sided) 95% -6.60 to -2.32
	Parameter Dispersion	Type: Standard Error of the mean Value: 1.09
	Estimation Comments	[Not specified]

▼ Statistical Analysis 3 ✔

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-5.27
	Confidence Interval	(2-Sided) 95% -7.41 to -3.13
	Parameter Dispersion	Type: Standard Error of the mean Value: 1.09
	Estimation Comments	[Not specified]

4. Secondary Outcome

Title:	Insomnia Severity Index (ISI)
Description:	The ISI is both a brief screening measure of insomnia and an outcomes measure for use in treatment research. It is a brief self-report instrument measuring the patient's perception of his or her insomnia, and it comprises 7 items. Each item is rated on a 0-4 scale and the total score ranges from 0 to 28. 0 = no symptoms and 28 = severe symptoms.
Time Frame:	Mean change from baseline to Week 8
Safety Issue?	No

Outcome Measure Data ✔ 4 Notes

Analysis Population Description

Mean change from baseline to Week 8 (FAS, LOCF, ANCOVA)

Arm/Group Title	Placebo (Orally, Once Daily)	Escitalopram 20 mg and Placebo (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)
Arm/Group Description:	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.
Number of Participants Analyzed	71	139	139	140
Mean (Standard Error) Units: Scores on a scale	-6.9 (0.7)	-10.0 (0.5)	-9.6 (0.5)	-10.6 (0.5)

Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Placebo (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-3.09
	Confidence Interval	(2-Sided) 95% -4.59 to -1.58
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.77
	Estimation Comments	[Not specified]

Statistical Analysis 2 ✔

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0006
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-2.64
	Confidence Interval	(2-Sided) 95% -4.15 to -1.14
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.77
	Estimation Comments	[Not specified]

▼ Statistical Analysis 3 ✓

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-3.61
	Confidence Interval	(2-Sided) 95% -5.13 to -2.10
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.77
	Estimation Comments	[Not specified]

5. Secondary Outcome

Title:	Sheehan Disability Scale (SDS): Family Subscale
▼ Description:	The SDS comprises self-rated items designed to measure impairment. The patient rates the extent to which his or her (1) work, (2) social life or leisure activities and (3) home life or family responsibilities are impaired on a 10-point visual analogue scales, on which 0 = normal functioning and 10 = severe functional impairment.
Time Frame:	Mean change from baseline to Week 8
Safety Issue?	No

▼ Outcome Measure Data ✓ 4 Notes

▼ Analysis Population Description

Mean change from baseline to Week 8 (FAS, LOCF, ANCOVA)

Arm/Group Title	Placebo (Orally, Once	Escitalopram 20 mg	Escitalopram 20 mg	Escitalopram 20 mg

	Daily)	and Placebo (Orally, Once Daily)	and Gaboxadol 5 mg (Orally, Once Daily)	and Gaboxadol 10 mg (Orally, Once Daily)
▼ Arm/Group Description:	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.
Number of Participants Analyzed	71	139	139	140
Mean (Standard Error) Units: Scores on a scale	-2.8 (0.02)	-4.0 (0.02)	-3.9 (0.02)	-4.1 (0.02)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Placebo (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-1.25
	Confidence Interval	(2-Sided) 95% -1.85 to -0.64
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.31
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✓

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0004
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-1.11
	Confidence Interval	(2-Sided) 95% -1.72 to -0.50
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.31
	Estimation Comments	[Not specified]

▼ Statistical Analysis 3 ✔

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-1.26
	Confidence Interval	(2-Sided) 95% -1.87 to -0.65
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.31
	Estimation Comments	[Not specified]

6. Secondary Outcome

Title:	SDS: Work Subscale
▼ Description:	The SDS comprises self-rated items designed to measure impairment. The patient rates the extent to which his or her (1) work, (2) social life or leisure activities and (3) home life or family responsibilities are impaired on a 10-point visual analogue scales, on which 0 = normal functioning and 10 = severe functional impairment.
Time Frame:	Mean change from baseline to Week 8
Safety Issue?	No

▼ Outcome Measure Data ✔ 4 Notes

▼ Analysis Population Description

Mean change from baseline to Week 8 (FAS, LOCF, ANCOVA)

Arm/Group Title	Placebo (Orally, Once Daily)	Escitalopram 20 mg and Placebo (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)

▼ Arm/Group Description:	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.
Number of Participants Analyzed	71	139	139	140
Mean (Standard Error) Units: Scores on a scale	-2.7 (0.03)	-3.8 (0.02)	-3.8 (0.02)	-4.0 (0.02)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Placebo (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0007
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-1.09
	Confidence Interval	(2-Sided) 95% -1.72 to -0.46
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.32
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0013
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-1.05
	Confidence Interval	(2-Sided) 95% -1.69 to -0.41
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.33
	Estimation Comments	[Not specified]

▼ Statistical Analysis 3 ✔

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-1.29
	Confidence Interval	(2-Sided) 95% -1.92 to -0.66
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.32
	Estimation Comments	[Not specified]

7. Secondary Outcome

Title:	SDS: Social Subscale
▼ Description:	The SDS comprises self-rated items designed to measure impairment. The patient rates the extent to which his or her (1) work, (2) social life or leisure activities and (3) home life or family responsibilities are impaired on a 10-point visual analogue scales, on which 0 = normal functioning and 10 = severe functional impairment.
Time Frame:	Mean change from baseline to Week 8
Safety Issue?	No

▼ Outcome Measure Data ✔ 4 Notes

▼ Analysis Population Description

Mean change from baseline to Week 8 (FAS, LOCF, ANCOVA)

Arm/Group Title	Placebo (Orally, Once Daily)	Escitalopram 20 mg and Placebo (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)

▼ Arm/Group Description:	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.
Number of Participants Analyzed	71	139	139	140
Mean (Standard Error) Units: Scores on a scale	-2.7 (0.03)	-3.9 (0.02)	-3.8 (0.02)	-4.1 (0.02)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Placebo (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0002
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-1.20
	Confidence Interval	(2-Sided) 95% -1.82 to -0.58
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.31
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0006
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-1.10
	Confidence Interval	(2-Sided) 95% -1.72 to -0.48
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.32
	Estimation Comments	[Not specified]

▼ Statistical Analysis 3 ✔

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-1.38
	Confidence Interval	(2-Sided) 95% -2.00 to -0.76
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.32
	Estimation Comments	[Not specified]

8. Secondary Outcome

Title:	Clinical Global Impression - Severity of Illness (CGI-S)
▼ Description:	The CGI-S provides the clinician's impression of the patient's current state of mental illness. The clinician uses his or her clinical experience of this patient population to rate the severity of the patient's current mental illness on a 7-point scale ranging from 1 (Normal - not at all ill) to 7 (among the most extremely ill patients).
Time Frame:	Mean change from baseline to Week 8
Safety Issue?	No

▼ Outcome Measure Data ✔ 4 Notes

▼ Analysis Population Description

Mean change from baseline to Week 8 (FAS, LOCF, ANCOVA)

Arm/Group Title	Placebo (Orally, Once Daily)	Escitalopram 20 mg and Placebo (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)

▼ Arm/Group Description:	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.
Number of Participants Analyzed	71	139	139	140
Mean (Standard Error) Units: Scores on a scale	-1.04 (0.13)	-1.65 (0.10)	-1.58 (0.10)	-1.76 (0.10)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Placebo (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.61
	Confidence Interval	(2-Sided) 95% -0.89 to -0.34
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.14
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✓

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.54
	Confidence Interval	(2-Sided) 95% -0.82 to -0.26
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.14
	Estimation Comments	[Not specified]

▼ Statistical Analysis 3 ✔

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.72
	Confidence Interval	(2-Sided) 95% -0.99 to -0.44
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.14
	Estimation Comments	[Not specified]

9. Secondary Outcome

Title:	Clinical Global Impression - Global Improvement (CGI-I)
▼ Description:	The CGI-I provides the clinician's impression of the patient's improvement (or worsening). The clinician assesses the patient's condition relative to a baseline on a 7-point scale ranging from 1 (very much improved) to 7 (very much worse).
Time Frame:	at Week 8
Safety Issue?	No

▼ Outcome Measure Data ✔ 4 Notes

▼ Analysis Population Description

At Week 8 (FAS, LOCF, ANCOVA)

Arm/Group Title	Placebo (Orally, Once Daily)	Escitalopram 20 mg and Placebo (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)

▼ Arm/Group Description:	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.
Number of Participants Analyzed	71	139	139	140
Mean (Standard Error) Units: Scores on a scale	2.97 (0.12)	2.21 (0.09)	2.35 (0.09)	2.26 (0.09)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Placebo (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.76
	Confidence Interval	(2-Sided) 95% -1.02 to -0.50
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.13
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✓

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.62
	Confidence Interval	(2-Sided) 95% -0.88 to -0.36
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.13
	Estimation Comments	[Not specified]

▼ Statistical Analysis 3 ✔

Statistical Analysis Overview	Comparison Groups	Placebo (Orally, Once Daily), Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.71
	Confidence Interval	(2-Sided) 95% -0.97 to -0.45
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.13
	Estimation Comments	[Not specified]

Adverse Events

Time Frame	8 weeks			
Additional Description				
Source Vocabulary Name	MedDRA 12.1			
Assessment Type	Non-systematic Assessment			
Arm/Group Title	Placebo (Orally, Once Daily)	Escitalopram 20 mg and Placebo (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)
▼ Arm/Group Description	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.

Serious Adverse Events

	Placebo (Orally, Once Daily)	Escitalopram 20 mg and Placebo (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)	Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	1/71 (1.41%)	0/140 (0%)	0/139 (0%)	0/140 (0%)
Infections and infestations				
Appendicitis [A]	1/71 (1.41%)	0/140 (0%)	0/139 (0%)	0/140 (0%)

Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA 12.1

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	1%			
	Placebo (Orally, Once Daily)	**Escitalopram 20 mg and Placebo (Orally, Once Daily)**	**Escitalopram 20 mg and Gaboxadol 5 mg (Orally, Once Daily)**	**Escitalopram 20 mg and Gaboxadol 10 mg (Orally, Once Daily)**
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	12/71 (16.9%)	22/140 (15.71%)	31/139 (22.3%)	19/140 (13.57%)
Gastrointestinal disorders				
Diarrhoea [A]	0/71 (0%)	2/140 (1.43%)	0/139 (0%)	0/140 (0%)
Nausea [A]	0/71 (0%)	1/140 (0.71%)	6/139 (4.32%)	2/140 (1.43%)
Infections and infestations				
Dermatitis allergic [A]	1/71 (1.41%)	0/140 (0%)	0/139 (0%)	0/140 (0%)
Influenza [A]	1/71 (1.41%)	1/140 (0.71%)	1/139 (0.72%)	2/140 (1.43%)
Rhinitis allergic [A]	1/71 (1.41%)	0/140 (0%)	0/139 (0%)	0/140 (0%)
Injury, poisoning and procedural complications				
Accidental overdose [A]	3/71 (4.23%)	4/140 (2.86%)	8/139 (5.76%)	3/140 (2.14%)
Investigations				
Blood pressure increased [A]	0/71 (0%)	2/140 (1.43%)	1/139 (0.72%)	1/140 (0.71%)
Nervous system disorders				
Headache [A]	4/71 (5.63%)	7/140 (5%)	5/139 (3.6%)	3/140 (2.14%)
Psychomotor hyperactivity [A]	0/71 (0%)	0/140 (0%)	0/139 (0%)	2/140 (1.43%)
Somnolence [A]	0/71 (0%)	0/140 (0%)	3/139 (2.16%)	1/140 (0.71%)
Psychiatric disorders				
Anxiety [A]	0/71 (0%)	3/140 (2.14%)	2/139 (1.44%)	3/140 (2.14%)
Insomnia [A]	3/71 (4.23%)	3/140 (2.14%)	4/139 (2.88%)	2/140 (1.43%)
Suicidal ideation [A]	0/71 (0%)	0/140 (0%)	1/139 (0.72%)	2/140 (1.43%)

Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA 12.1

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The main publication has to be published before any sub-publications.

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