Results of the incompleted clinical trial

"Glutamatergic medication in the treatment of obsessive compulsive disorder (OCD) and autism spectrum disorder (ASD)"

EudraCT Number: 2014-003080-38

SUMMARY

In total, seven patients were included in the study. N=4 (57.1%) participants were treated with verum (memantine) and n=3 (42.9%) received placebo. No serious adverse events (SAEs) were reported.

STUDY POPULATION

Table 1: Demographic data of participants

Patient ID	Study site	Diagnosis	Gender	Age	Concomitant medication	Treatment
1	London	OCD	female	14	Sertraline	Verum
2	London	OCD + ASD	male	15	Sertraline, melatonin	Verum
3	Mannheim	OCD	female	17	Sertraline	Verum
4	Mannheim	OCD	female	15	Sertraline	Verum
5	Nijmegen	ASD	male	6	none	Placebo
6	Nijmegen	ASD	male	9	Risperidone, melatonin, methylphenidate	Placebo
7	Nijmegen	OCD	female	14	none	Placebo

No: Number; OCD: obsessive-compulsive disorder; ASD: autism spectrum disorder

RESULTS

Table 2. CY-BOCS scores (total and subscores obessions and compulsions) for all included participants (receiving memantine or placebo) at all timepoints where CY-BOCS was assessed and score reduction from baseline (visit 3) to end of treatment period (visit 9 or early discontinuation)

Study period			**Double-blind treatment**					**Down-titration**		**Early termination visit**		
Visit number			**V3**	V4	V5	V6	V8	**V9**	V10	**ETV**		**Reduction**
Memantine	ID1	Total	**26**	17	26	24	23	**21**	24	-		**19.2 %**
		Obs.	***12***	*9*	*14*	*12*	*12*	***11***	*11*	-		***8.4 %***
		Comp.	***14***	*8*	*12*	*12*	*11*	***10***	*13*	-		***28.6 %***
	ID2	Total	**21**	20	19	21	16	**12**	14	-		**42.9 %**
		Obs.	***9***	*10*	*10*	*10*	*8*	***6***	*7*	-		***33.3 %***
		Comp.	***12***	*10*	*9*	*11*	*8*	***6***	*7*	-		***50.0 %***
	ID3	Total	**30**	28	26	25	-	**-**	-	**23**		**23.3 %**
		Obs.	***15***	*14*	*14*	*13*	-	***-***	-	***12***		***20.0 %***
		Comp.	***15***	*14*	*12*	*12*	-	***-***	-	***11***		***26.7 %***
	ID4	Total	**22**	24	22	22	18	**17**	16	-		**22.7 %**
		Obs.	***11***	*12*	*10*	*11*	*9*	***8***	*8*	-		***27.3 %***
		Comp.	***11***	*12*	*12*	*11*	*9*	***9***	*8*	-		***18.2 %***
Placebo	ID5	Total	**0**	0	0	0	0	**0**	0	-		**0 %**
		Obs.	***0***	*0*	*0*	*0*	*0*	***0***	*0*	-		***0 %***
		Comp.	***0***	*0*	*0*	*0*	*0*	***0***	*0*	-		***0 %***
	ID6	Total	**8**	8	8	8	7	**7**	7	-		**12.5 %**
		Obs.	***0***	*0*	*0*	*0*	*0*	***0***	*0*	-		***0 %***
		Comp.	***8***	*8*	*8*	*8*	*7*	***7***	*7*	-		***12.5 %***
	ID7	Total	**35**	35	35	35	35	**-**	-	**30**		**14.3 %**
		Obs.	***18***	*18*	*18*	*18*	*18*	***-***	-	***15***		***16.7 %***
		Comp.	***17***	*17*	*17*	*17*	*17*	***-***	-	***15***		***11.8 %***

Total = CY-BOCS total score; Obs. = CY-BOCS obsession subscore; Comp. = CY-BOCS compulsion subscore

Table 3. Clinical Global Impression-Severity of all included participants (receiving memantine or placebo) at all timepoints where scale was assessed

Study period		**Screening**	**Double-blind treatment**						**Down-titration**		**Early termination visit**
Visit number		V1	V3	V4	V5	V6	V7	V8	V9	V10	ETV
Memantine	**ID1**	5	5	5	5	5	4	4	4	4	
	ID2	4	4	4	4	4	4	4	3	3	
	ID3	6	6	6	6	6	-	-	-	-	6
	ID4	5	5	5	5	5	5	4	3	3	
Placebo	**ID5**	5	5	5	4	4	4	4	4	4	
	ID6	5	5	5	5	5	4	5	4	5	
	ID7	4	5	5	5	5	5	5	-	-	5

3 = mildly ill; 4 = moderately ill; 5 = markedly ill; 6 = severely ill

Table 4. Clinical Global Impression-Improvement of all included participants (receiving memantine or placebo) at all timepoints where scale was assessed

Study period		**Double-blind treatment**					**Down-titration**		**Early termination visit**
Visit number		V4	V5	V6	V7	V8	V9	V10	ETV
Memantine	**ID1**	3	4	4	4	4	5	4	
	ID2	4	4	3	3	3	2	5	
	ID3	4	3	3	-	-	-	-	3
	ID4	4	3	3	3	2	2	2	
Placebo	**ID5**	4	3	3	3	3	3	4	
	ID6	4	4	3	2	3	3	3	
	ID7	4	4	4	4	4	-	-	4

2 = much improved; 3 = minimally improved; 4 = no change; 5 = minimally worse

Table 5. Children's Global Assessment Scale (in percent) of all included participants (receiving memantine or placebo) at all timepoints where scale was assessed

Study period		**Double-blind treatment**		**Down-titration**	**Early termination visit**
Visit number		V3	V6	V9	ETV
Memantine	ID1	44	50	52	
	ID2	56	59	65	
	ID3	38	31-40	-	31-40
	ID4	39	41	63	
Placebo	ID5	50	55	55	
	ID6	40	45	50	
	ID7	50	60	-	50

ADVERSE EVENTS

Table 6: Study drug-related adverse events

	Memantine (N=4)		**Placebo (N=3)**	
	n	**N (%)**	**n**	**N (%)**
Irritability	0	0	1	1 (33.3)
Cognition	2	1 (25)	0	0
Sedation	6	1 (25)	0	0
Sleep problems	1	1 (25)	2	1 (33.3)
Feeling hungry	0	0	4	1 (33.3)
Dizziness	0	0	2	1 (33.3)
Stomach ache	5	1 (25)	0	0
Constipation	3	1 (25)	0	0
Vomiting	3	1 (25)	0	0
Headache	2	2 (50)	2	1 (33.3)
Total	22	-	11	-

n: number of reported events; N: number of participants

No serious adverse events (SAEs); no early discontinuations due to adverse events.