

H. Lundbeck A/S
9 Ottiliavej DK-2500 Valby
Copenhagen Denmark

Tel +45 3630 1311
Fax +45 3630 1354

E-mail kaal@lundbeck.com
www.lundbeck.com

*gone out
1/27/01*



By courier mail

Ivan Gergel
Forest Laboratories Inc.
909 Third Avenue
New York, NY 10022-4731
USA

*file Alexander
study
94404*

Date 16 July 2001

Our ref KAAL/LIMA
Your ref

*Cherie Ficker,
Paul Tuxo,
Ralph Huhns
L. Olcott
Jane Wu*

Study 94404 - Study results - Confidential

Dear Ivan

Please find enclosed the results of study 94404, which must be treated strictly confidentially.

If you have any questions, please do not hesitate to contact me or Per Tanghøj.

Best regards

Karl
Karoline Als

CBR No. 05769013



A4.5

CONFIDENTIAL

MDL-FORP0010491

Summary of Patient Disposition: ARPS

Patients Randomised	124		120		244	
Patients Treated	121		112		233	
Patients Completed	79	65.3%	74	66.1%	153	65.7%
Patients Withdrawn from APTS	42	34.7%	38	33.9%	80	34.3%
Patient Data Sets:						
Patients with AEs:						
All Patients Randomised Set (APRS)	124		120		244	
All Patients Treated Set (APTS)	121		112		233	
Full Analysis Set (FAS)	115		108		223	
Per Protocol Set (PPS)	104		91		195	

94404 STD2 16JUL2001:14:15:42

Summary of Patient Demographics: APTS

		121		112		233	
PATIENTS TREATED		121		112		233	
Patient Sex	Male	31	25.6%	29	25.9%	60	25.8%
	Female	90	74.4%	83	74.1%	173	74.2%
Age	N	121		112		233	
	Mean	16		16		16	
	Median	16		16		16	
	SD	1		1		1	
	Min	13		13		13	
	Max	18		18		18	
Patient Race	Caucasian	117	96.7%	110	98.2%	227	97.4%
	Asian	3	2.5%	1	0.9%	4	1.7%
	Other	1	0.8%	1	0.9%	2	0.9%

94404 ST06 12JUL2001:14:34:39

Baseline Height, Weight and Body Mass Index (BMI): APTS

		121	112	233
PATIENTS TREATED				
Subject Height	N	118	111	230
	Mean	168	168	168
	Median	167	168	168
	SD	8	9	8
	Min	153	136	138
	Max	186	199	199
Subject Weight	N	118	110	228
	Mean	63	62	63
	Median	62	60	60
	SD	14	12	13
	Min	44	29	28
	Max	118	100	118
Subject Body Mass Index (Baseline)	N	118	110	228
	Mean	22	22	22
	Median	22	21	21
	SD	4	4	4
	Min	16	15	15
	Max	39	36	39

94404 ST07 12JUL2001:14:34:47

Baseline Height, Weight and Body Mass Index (BMI): APTS:Males

PATIENTS TREATED		31	29	60
Subject Height	N	30	28	58
	Mean	175	177	176
	Median	175	178	176
	SD	9	9	9
	Min	153	160	153
	Max	196	199	199
Subject Weight	N	30	28	58
	Mean	68	70	69
	Median	65	68	66
	SD	16	13	14
	Min	48	45	45
	Max	112	100	112
Subject Body Mass Index (Baseline)	N	30	28	58
	Mean	22	22	22
	Median	21	21	21
	SD	5	4	4
	Min	17	17	17
	Max	35	36	36

94404 ST08 12JUL2001:14:34:52

Baseline Height, Weight and Body Mass Index (BMI): APTS:Females

PATIENTS TREATED		90	83	173
Subject Height	N	89	83	172
	Mean	168	166	166
	Median	165	166	166
	SD	6	6	6
	Min	153	138	138
	Max	180	179	180
Subject Weight	N	88	82	170
	Mean	81	59	80
	Median	60	58	59
	SD	13	11	12
	Min	44	29	29
	Max	118	91	118
Subject Body Mass Index (Baseline)	N	88	82	170
	Mean	22	21	22
	Median	22	21	21
	SD	4	3	4
	Min	16	15	15
	Max	39	30	39

94404 ST09 12JUL2001:14:34:57

Withdrawals from Study by Primary Reason: APTS

Patients Treated	121		112		233	
Patients Completed	79	65.3%	74	66.1%	153	65.7%
Patients Withdrawn from APTS	42	34.7%	38	33.9%	80	34.3%
Primary Reason:						
Adverse Event(s)	12	9.9%	9	8.0%	21	9.0%
Lack of efficacy	11	9.1%	18	16.1%	29	12.4%
Non-compliance with study medication	5	4.1%	1	0.9%	6	2.6%
Protocol violation	1	0.8%			1	0.4%
Withdrawal of consent	4	3.3%	6	5.4%	10	4.3%
Lost to follow up	3	2.5%	2	1.8%	5	2.1%
Administrative reason(s)	1	0.8%			1	0.4%
Other reason(s)	5	4.1%	2	1.8%	7	3.0%

94404 ST04 12JUL2001:14:34:26

Withdrawals from Study by All Reasons: APTS

Patients Treated	121		112		233	
Patients Completed	79	65.3%	74	66.1%	153	65.7%
Patients Withdrawn from APTS	42	34.7%	38	33.9%	80	34.3%
Reason:						
Adverse Event(s)	12	9.9%	9	8.0%	21	9.0%
Lack of efficacy	20	16.5%	25	22.3%	45	19.3%
Non-compliance with study medication	7	5.8%	2	1.8%	9	3.9%
Protocol violation	1	0.8%	1	0.9%	2	0.9%
Withdrawal of consent	10	8.3%	13	11.6%	23	9.9%
Lost to follow up	4	3.3%	2	1.8%	6	2.6%
Administrative reason(s)	1	0.8%			1	0.4%
Other reason(s)	10	8.3%	8	5.4%	18	8.9%

94404 ST05 12JUL2001:14:34:33

Patients Treated by Visit: APTS

Patients Treated	121		112		233	
Patients Completed	79	65.3%	74	66.1%	153	65.7%
Patients Withdrawn from APTS	42	34.7%	38	33.6%	80	34.3%
Patients Attending at:						
Screening(Week 0)	121	100%	112	100%	233	100%
Visit 2 (Baseline)	121	100%	112	100%	233	100%
Visit 3 (Week 1)	116	95.9%	110	98.2%	226	97.0%
Visit 4 (Week 2)	114	94.2%	109	97.3%	223	95.7%
Visit 5 (Week 5)	106	87.6%	91	81.3%	197	84.5%
Visit 6 (Week 9)	88	72.7%	82	73.2%	170	73.0%
Visit 7 (Week 12)	83	68.6%	74	66.1%	157	67.4%

94404 ST03 12JUL2001:14:34:19

**Kiddle-Sads Total Score (FAS)
nominal visits data set**

CIT	0	115	32.47	5.01	32.00	19	46
	14	113	27.95	6.80	28.00	9	43
	35	109	25.22	7.73	25.00	9	47
	63	95	22.15	8.59	20.00	9	51
	84	83	19.61	8.43	18.00	9	48
PBO	0	108	32.29	5.41	32.00	18	42
	14	107	27.87	6.18	28.00	13	46
	35	97	25.06	7.28	24.00	11	48
	63	83	21.87	7.79	21.00	9	44
	84	78	19.49	8.71	18.00	2	46

@ nominal visits

94404 ET01 12JUL2001:13:34:02

**Kiddie-Sads Total Score (FAS)
nominal visits data set**

CIT	0	115	32.47	5.01	32.00	19	46
	14	115	27.82	6.89	28.00	9	43
	35	115	25.35	7.99	25.00	9	47
	63	113	23.52	9.09	23.00	9	51
	84	115	22.41	9.41	21.00	9	48
PBO	0	108	32.29	5.41	32.00	16	42
	14	108	27.89	8.15	28.00	13	48
	35	108	25.56	7.44	25.00	11	48
	63	108	23.71	8.64	23.00	9	48
	84	108	22.55	9.99	22.00	2	48

@ nominal visits

94404 ET02 12JUL2001:13:34:14

**MADRS Total Score (FAS)
nominal visits data set**

CIT	0	96	29.55	5.50	29.00	18	49
	14	94	22.98	7.75	23.00	0	37
	35	93	20.88	9.98	21.00	0	46
	63	80	16.36	10.59	15.00	0	45
	84	71	13.77	9.88	12.00	0	44
PBO	0	91	29.52	5.94	30.00	9	43
	14	90	23.83	8.15	24.00	5	46
	35	87	21.22	9.48	21.00	0	46
	63	77	17.48	10.09	18.00	0	44
	84	71	14.83	11.05	12.00	0	48

@ nominal visits

94404 ET04 12JUL2001:13:34:26

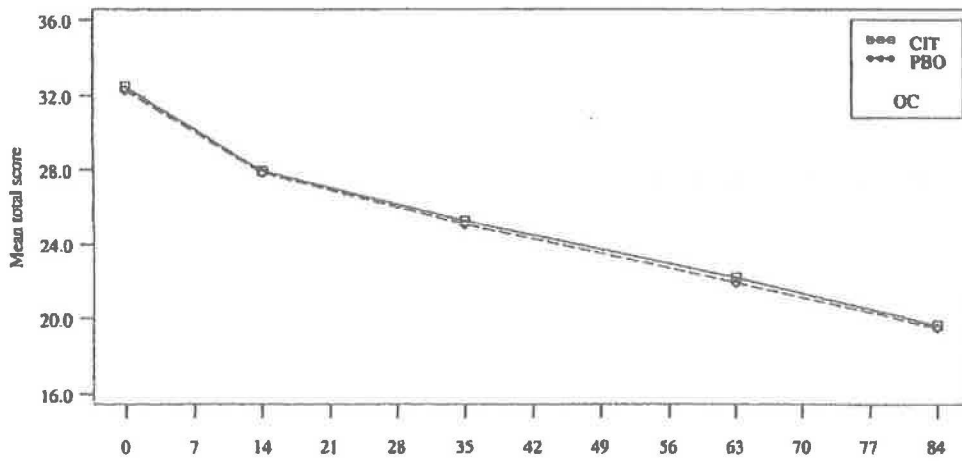
**MADRS Total Score (FAS)
nominal visits data set**

CIT	0	96	29.55	5.50	29.00	18	49
	14	96	22.81	7.96	23.00	0	37
	35	96	20.90	10.11	21.00	0	46
	83	94	18.13	11.25	17.00	0	46
	84	96	16.80	11.09	15.50	0	46
PBO	0	91	29.52	5.94	30.00	9	43
	14	91	23.73	8.15	24.00	5	46
	35	91	21.13	9.46	21.00	0	46
	83	91	18.91	11.13	18.00	0	46
	84	91	17.55	12.57	15.00	0	48

@ nominal visits

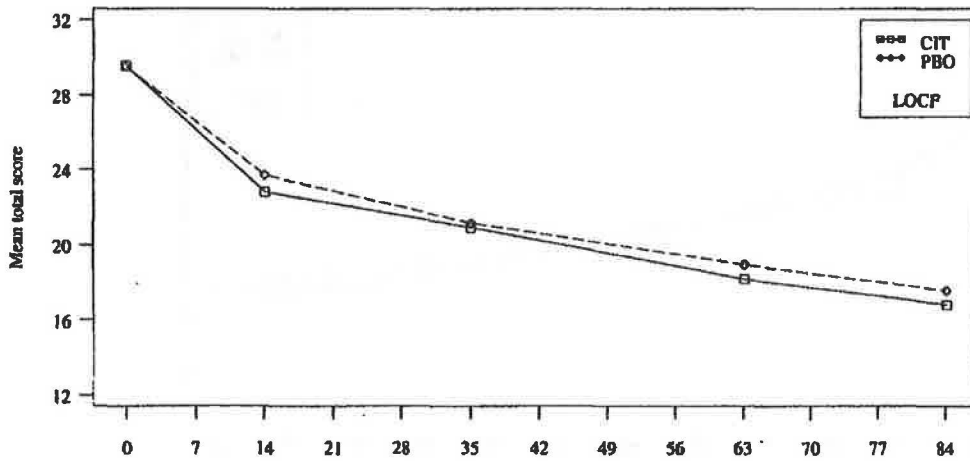
94404 ET05 12JUL2001:13:34:32

Kiddie-Sads Total Score (FAS)
nominal visits data set



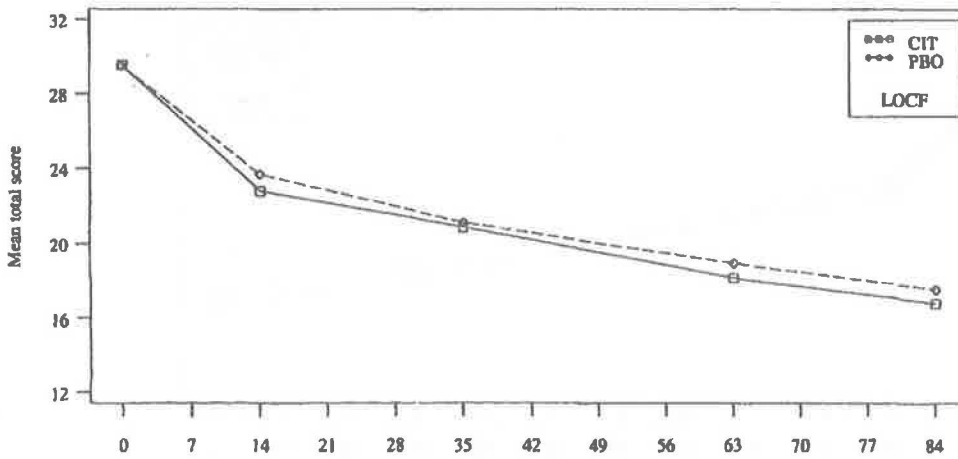
94404 ET01/BF01 12JUL2001:13:34:02

MADRS Total Score (FAS)
nominal visits data set



94404 ET05/EP05 12JUL2001:13:34:32

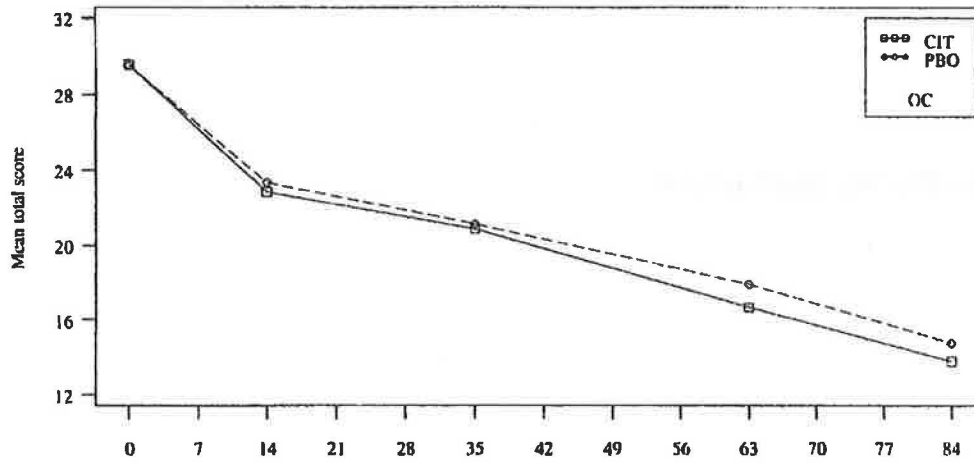
MADRS Total Score (FAS)
nominal visits data set



94404 ET05/BF05 12JUL2001:13:34:32

CONFIDENTIAL

MADRS Total Score (FAS)
visit windows data set



94404 ET06/EF06 12JUL2001-13:34:38

**Treatment Difference of the Adjusted Mean Changes from Baseline In
Kiddle-SADS Total Score (FAS)
(nominal visits data set)**

|--|--|--|--|--|--|--|--|--|

CIT	14	111	-5.67	-0.14	0.71	-1.53	1.26	0.848
	35	109	-7.52	0.32	1.04	-1.74	2.38	0.762
	63	95	-9.89	0.17	1.23	-2.26	2.80	0.891
	84	83	-12.62	0.45	1.27	-2.07	2.97	0.723

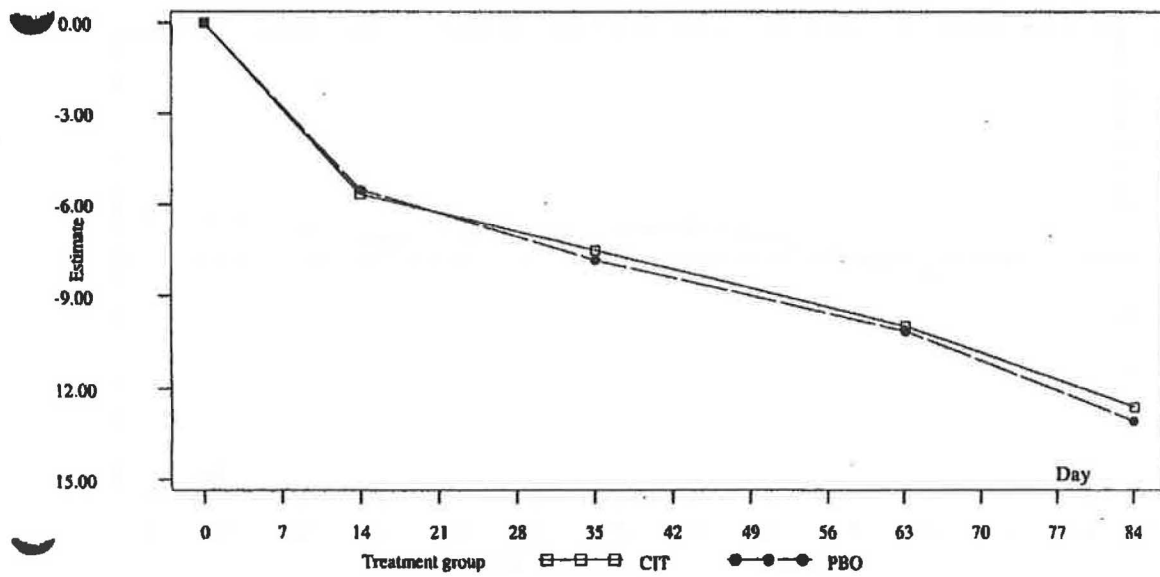
PBO	14	107	-5.53					
	35	98	-7.83					
	63	83	-10.15					
	84	78	-13.07					

@ nominal visits OC

Model: ANCOVA with treatment and Centre as factors
and baseline score as covariate

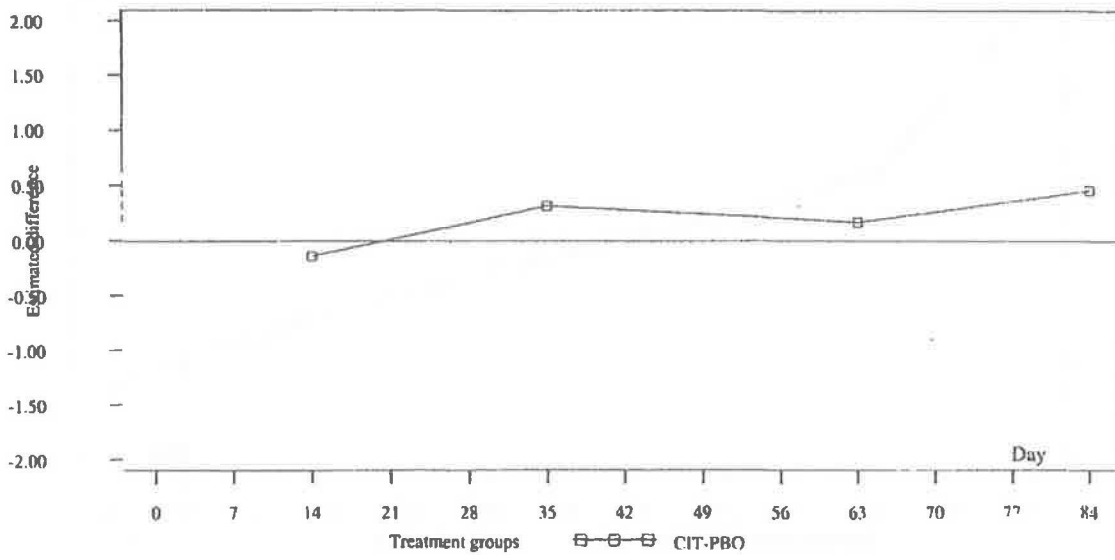
94404 ET07 12JUL2001:14:03:20

Adjusted Mean Changes from Baseline in Kiddie-SADS Total Score (FAS)
(nominal visits data set)



94404 ET07/EF07A 16JUL2001:14:14:51

Treatment Difference of the Adjusted Mean Changes from Baseline in
Kiddie-SADS Total Score (FAS)
(nominal visits data set)



94404 ET07/EP07 12JUL2001 14:24:55

**Treatment Difference of the Adjusted Mean Changes from Baseline in
Kiddle-SADS Total Score at Primary Endpoint (FAS, OC)
nominal visits data set**

CIT	115	-10.83	-0.22	1.22	-2.64	2.19	0.854
PBO	108	-10.60					

Model: ANCOVA with treatment and Centre as factors
and baseline score as covariate

94404 ET08 12JUL2001:14:25:16

**Treatment Difference of the Adjusted Mean Changes from Baseline in
Kiddle-SADS Total Score at Primary Endpoint (FAS, LOCF)
nominal visits data set**

CIT	112	-11.19	-0.39	1.23	-2.81	2.03	0.751
PBO	107	-10.80					

Model: ANCOVA with treatment and Centre as factors
and baseline score as covariate

94404 ET09 12JUL2001:14:25:28

**Treatment Difference of the Adjusted Mean Changes from Baseline in
MADRS Total Score (FAS)
(nominal visits data set)**

|--|--|--|--|--|--|--|--|--|

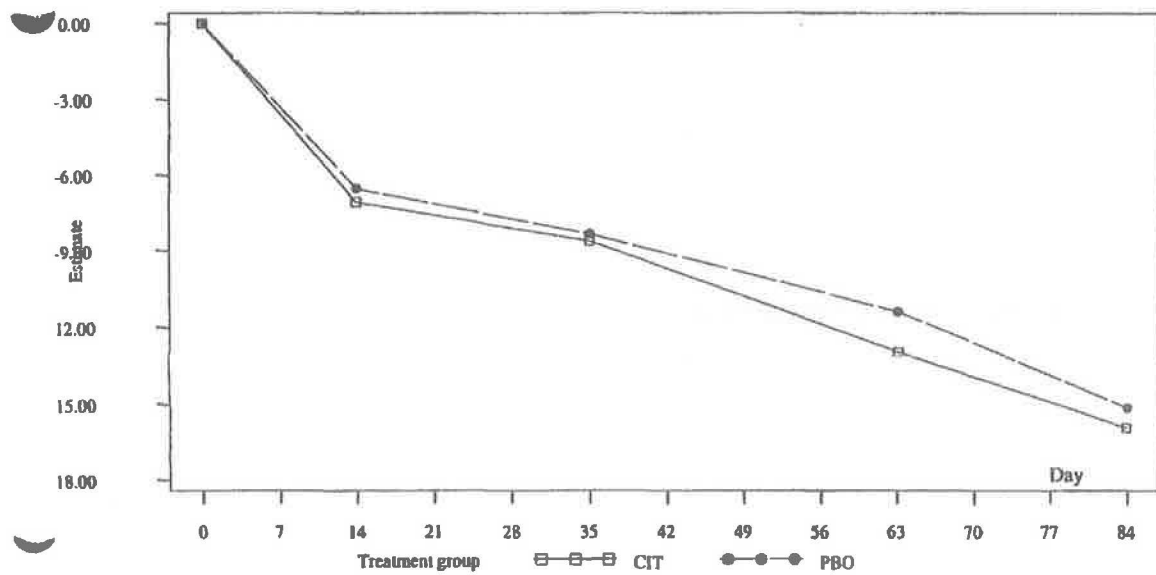
CIT	14	92	-7.03	-0.55	1.02	-2.55	1.46	0.591
	35	93	-8.61	-0.30	1.50	-3.26	2.66	0.842
	63	80	-12.99	-1.59	1.70	-4.95	1.77	0.351
	84	71	-15.93	-0.74	1.73	-4.17	2.68	0.667
PBO	14	90	-6.48					
	35	86	-8.31					
	63	77	-11.40					
	84	71	-15.18					

@ nominal visits DC

Model: ANCOVA with treatment and Centre as factors
and baseline score as covariate

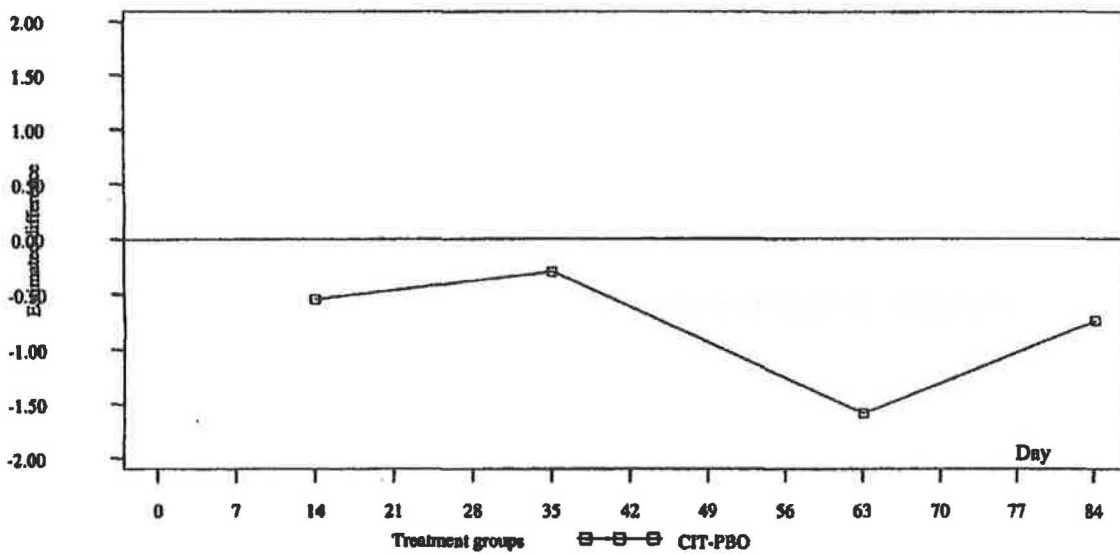
94404 ET10 12JUL2001:14:33:27

Adjusted Mean Changes from Baseline in MADRS Total Score (FAS)
(nominal visits data set)



94404 ET10/BP10A 16JUL2001:14:15:22

Treatment Difference of the Adjusted Mean Changes from Baseline in
MADR5 Total Score (FAS)
(nominal visits data set)



94404 ET10/EP10 12JUL2001:14:33:27

**Treatment Difference of the Adjusted Mean Changes from Baseline in
MADRS Total Score at Primary Endpoint (FAS, OC)
nominal visits data set**

--	--	--	--	--	--	--	--

CIT	96	-13.40	-0.65	1.69	-3.99	2.68	0.699
PBO	91	-12.75					

Model: ANCOVA with treatment and Centre as factors
and baseline score as covariate

94404 ET11 12JUL2001:14:33:46

**Treatment Difference of the Adjusted Mean Changes from Baseline in
MADRS Total Score at Primary Endpoint (FAS, LOCF)
nominal visits data set**

CIT	93	-13.89	-0.99	1.70	-4.34	2.36	0.560
P80	90	-12.90					

Model: ANCOVA with treatment and Centre as factors
and baseline score as covariate

94404 ET12 12JUL2001:14:33:57