Laser Lipo Ltd

K130341 510(k)

Strawberry and

Strawberry & Cream

Clinical Trial Protocol

Conducted at:

The Heath House Clinic,

Crockham Hill, Edenbridge, Kent, UK.

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1.   The *"Heath House"* Clinic

The "Heath House Clinic" is an operational beauty clinic. It is located on the first floor of the building. The clinic is a 2 roomed treatment salon that offers Laser Class 4 hair removal, laser inch loss treatments and a range of beauty treatments. The clinic compliments Laser Lipo Ltd as a perfect test site and location for training. The staff involved are all qualified to NVQ level III.

2. Treatment Consolidated Data

Heath House Clinic Double Blind Clinical Study - *Strawberry* Inch Loss- July/Aug 2013. Confidential.

Heath House Clinic - "Strawberry" Inch Loss Clinical Study consolidated results.

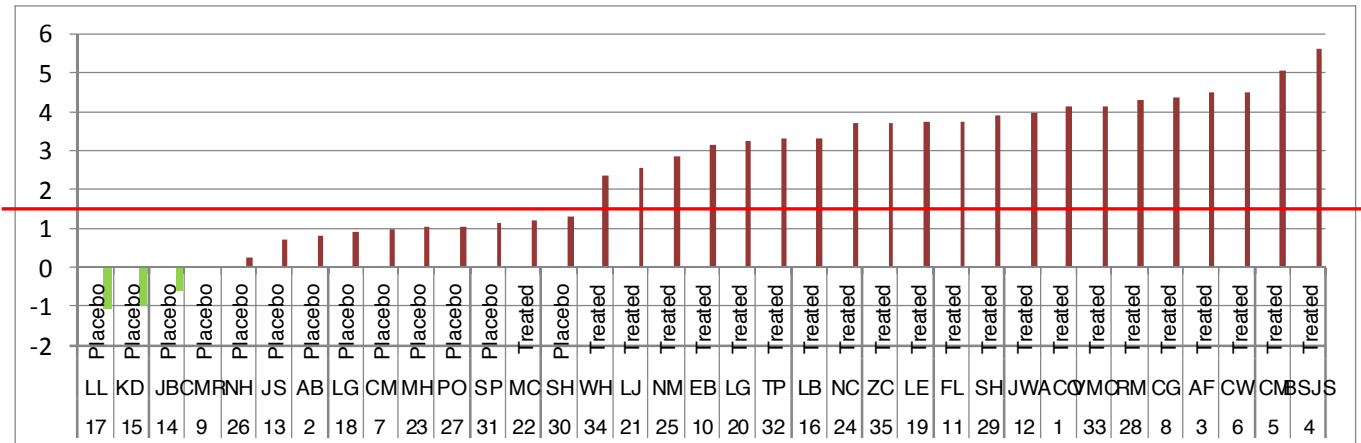| Subject No.:	Initials:	Treatment type:	Gender:	Age:	Weight loss: (Lbs)	BMI change:	Waist reduction: (In)	Reached success of 1.6in.	Notes / comments:
					Change over course of 8 treatments:				
1	ACO	Treated	F	20	5.0	0.9	4.1	Y	Only 6 visits
2	AB	Placebo	F	47	3.0	0.4	0.8	N	
3	AF	Treated	F	42	6.2	0.9	4.5	Y	
4	BSJS	Treated	F	36	4.8	0.7	5.6	Y	
5	CM	Treated	F	41	0.8	0.1	5.1	Y	
6	CW	Treated	F	27	7.4	1.4	4.5	Y	
7	CM	Placebo	M	48	2.5	0.4	1.0	N	
8	CG	Treated	F	31	5.2	0.9	4.4	Y	
9	CMR	Placebo	M	54	0	0.0	0.0	N	0 visits.
10	EB	Treated	F	20	0.8	0.1	3.1	Y	
11	FL	Treated	F	47	0.8	0.1	3.8	Y	
12	JW	Treated	F	52	4.8	1.0	4.0	Y	
13	JS	Placebo	F	57	4.0	0.7	0.7	N	
14	JB	Placebo	M	31	-1.0	-0.2	-0.6	N	
15	KD	Placebo	F	40	-2.0	-0.4	-1.0	N	
16	LB	Treated	F	29	1.0	0.2	3.3	Y	
17	LL	Placebo	F	33	-1.0	-0.2	-1.0	N	
18	LG	Placebo	F	25	2.0	0.3	0.9	N	
19	LE	Treated	F	55	5.4	1.0	3.7	Y	
20	LG	Treated	F	31	0.0	0.0	3.3	Y	
21	LJ	Treated	F	34	4.4	0.8	2.6	Y	
22	MC	Treated	M	27	1.2	0.2	1.2	N	
23	MH	Placebo	M	76	2.0	0.3	1.1	N	
24	NC	Treated	F	43	3.0	0.5	3.7	Y	
25	NM	Treated	F	22	3.0	0.5	2.9	Y	
26	NH	Placebo	F	76	1.0	0.2	0.3	N	Only 4 visits.
27	PO	Placebo	M	49	2.0	0.3	1.1	N	
28	RM	Treated	M	43	4.0	0.6	4.3	Y	
29	SH	Treated	F	31	4.0	0.7	3.9	Y	
30	SH	Placebo	M	24	3.8	0.6	1.3	N	
31	SP	Placebo	F	30	2.0	0.3	1.1	N	
32	TP	Treated	F	28	3.2	0.5	3.3	Y	
33	VMC	Treated	F	34	2.6	0.4	4.1	Y	
34	WH	Treated	F	39	1.6	0.2	2.4	Y	
35	ZC	Treated	F	26	3.8	0.6	3.7	Y	

Number of subjects in total:	35		Number of treated subjects:	22	
Number that attended all 8 treatments:	32		Number of placebo subjects:	13	
Number of female subjects:	27		Number of treated that achieved success:	21	
Number of male subjects:	8		Number of placebos that achieved success	0	
Subject study BMI range:	20.4	34.7	Subject age range:	20	76
Number of subjects that attended all 8 treatments and achieved the success criteria				20	95%

2. Treatment Data and Charts

Chart displaying the inch loss results for all subjects.
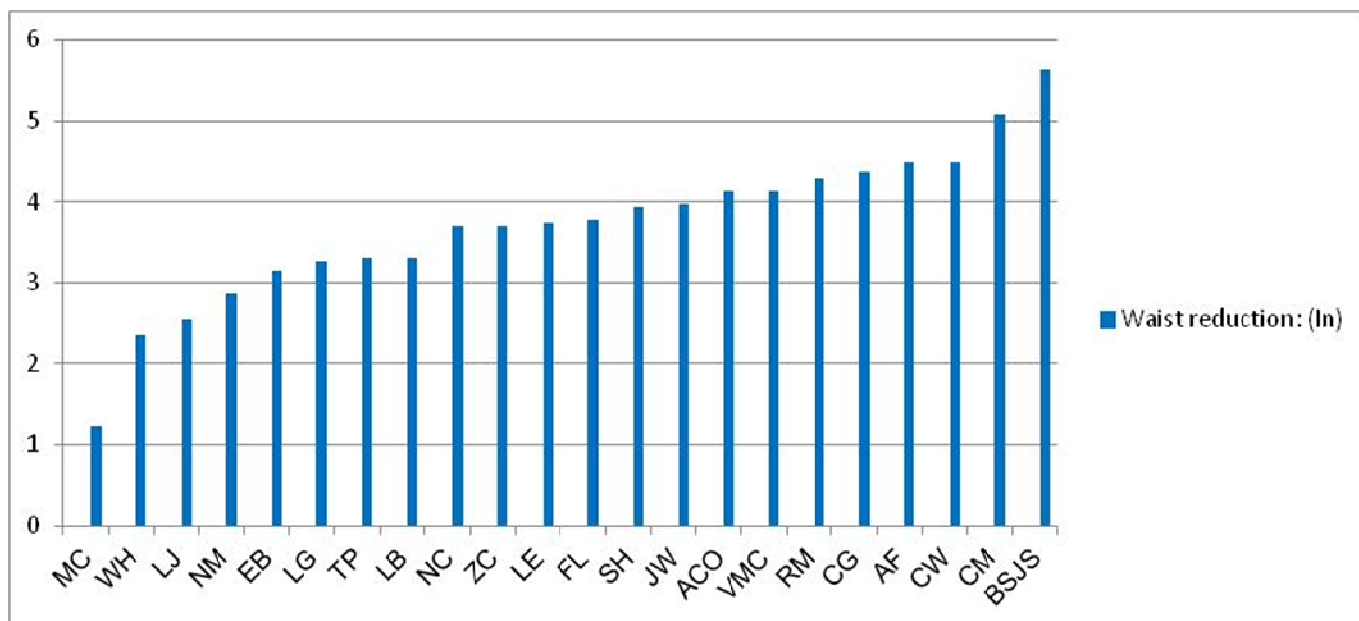

The red line above shows the 1.6in success criteria point. The only treated subject to not reach this level was MC (No. 22).

Subject No.:	Initials:	Treatment type:	Waist reduction: (In)
17	LL	Placebo	-1.0
15	KD	Placebo	-1.0
14	JB	Placebo	-0.6
9	CMR	Placebo	0.0
26	NH	Placebo	0.3
13	JS	Placebo	0.7
2	AB	Placebo	0.8
18	LG	Placebo	0.9
7	CM	Placebo	1.0
23	MH	Placebo	1.1
27	PO	Placebo	1.1
31	SP	Placebo	1.1
22	**MC**	**Treated**	**1.2**
30	SH	Placebo	1.3
34	WH	Treated	2.4
21	LJ	Treated	2.6
25	NM	Treated	2.9
10	EB	Treated	3.1
20	LG	Treated	3.3
32	TP	Treated	3.3
16	LB	Treated	3.3
24	NC	Treated	3.7
35	ZC	Treated	3.7
19	LE	Treated	3.7
11	FL	Treated	3.8
29	SH	Treated	3.9
12	JW	Treated	4.0
1	ACO	Treated	4.1
33	VMC	Treated	4.1
28	RM	Treated	4.3
8	CG	Treated	4.4
3	AF	Treated	4.5
6	CW	Treated	4.5
5	CM	Treated	5.1
4	BSJS	Treated	5.6

2. Treatment Data and Charts

Chart displays inch loss achieved with only the treated subjects.

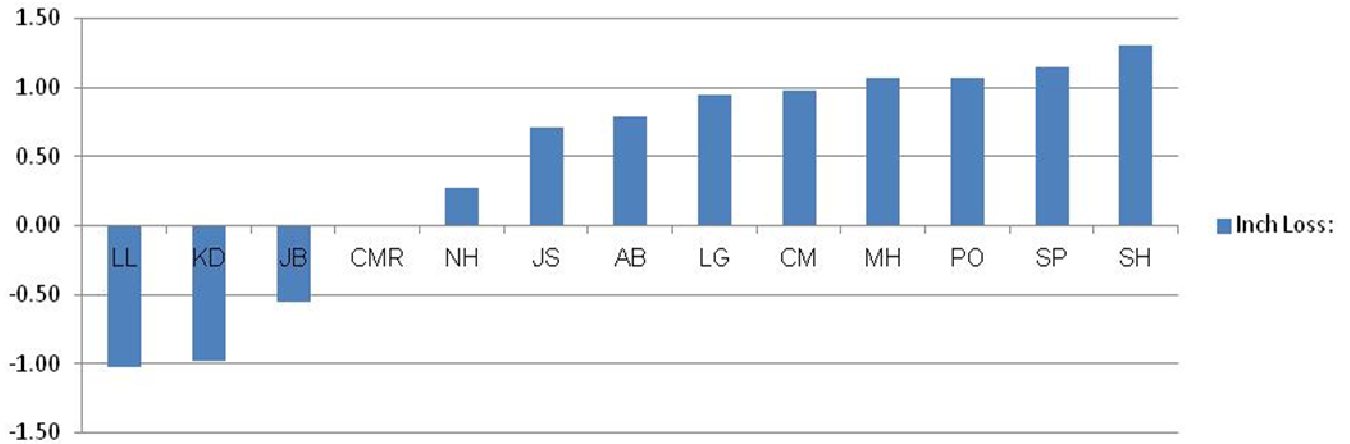

Of the treated subjects, one failed to pass the success criteria of 1.6in (4cm).
The average inch loss of all 22 treated subjects was 3.7in (9.4cm).

Inch loss results for all 'Treated' Subjects.			
Subject No.:	Initials:	Treatment type:	Waist reduction: (In)
22	MC	Treated	1.2
34	WH	Treated	2.4
21	LJ	Treated	2.6
25	NM	Treated	2.9
10	EB	Treated	3.1
20	LG	Treated	3.3
32	TP	Treated	3.3
16	LB	Treated	3.3
24	NC	Treated	3.7
35	ZC	Treated	3.7
19	LE	Treated	3.7
11	FL	Treated	3.8
29	SH	Treated	3.9
12	JW	Treated	4.0
1	ACO	Treated	4.1
33	VMC	Treated	4.1
28	RM	Treated	4.3
8	CG	Treated	4.4
3	AF	Treated	4.5
6	CW	Treated	4.5
5	CM	Treated	5.1
4	BSJS	Treated	5.6

2. Treatment Data and Charts

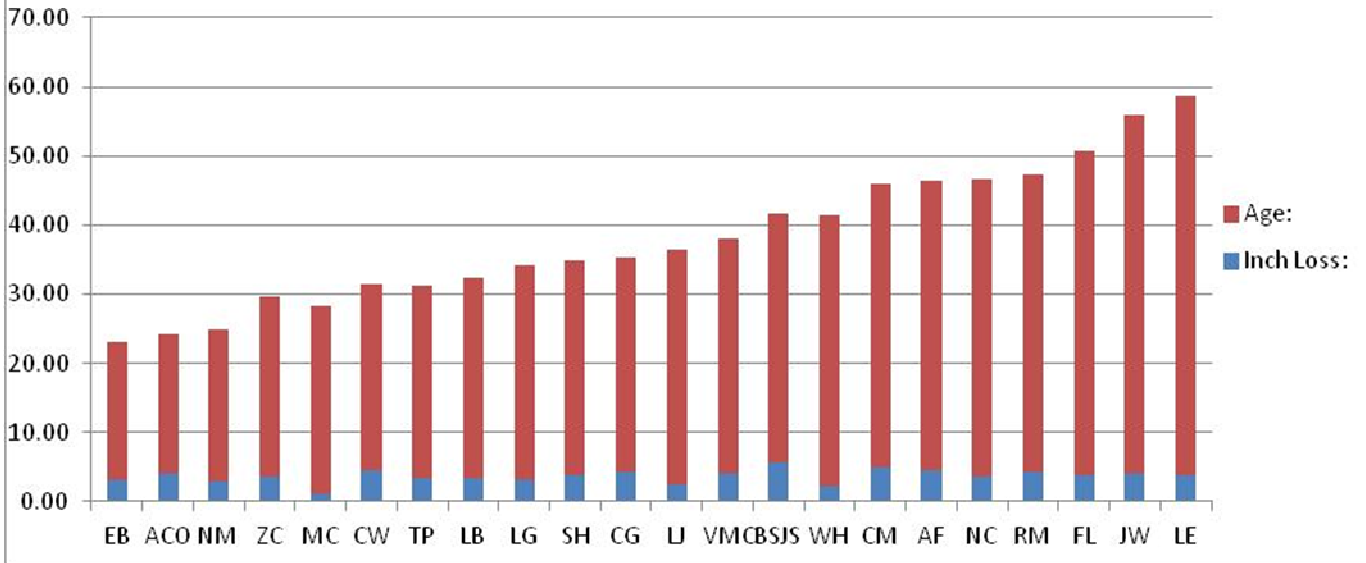## Chart shows the Inch Loss results for the Placebo Group.
(Average 0.83in)

Not one of the placebo subjects achieved the success criteria of 1.6in (cm) and in fact 3 of the placebo subjects gained in circumference, despite carrying out the cardiovascular exercise.

Placebo subjects:	
Subject Intials:	Inch Loss:
LL	-1.02
KD	-0.98
JB	-0.55
CMR	0.00
NH	0.28
JS	0.71
AB	0.79
LG	0.94
CM	0.98
MH	1.06
PO	1.06
SP	1.14
SH	1.30

2. Treatment Data and Charts
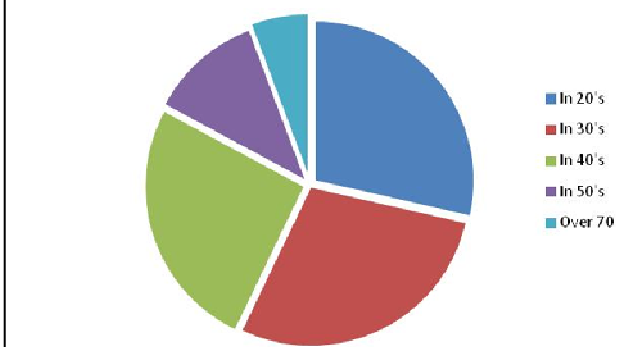

Chart shows Treated subject ages and results.

With an age range from 20 to 76 years the study group covers a huge spectrum. The results show that age is not a consideration regarding the achieved results.
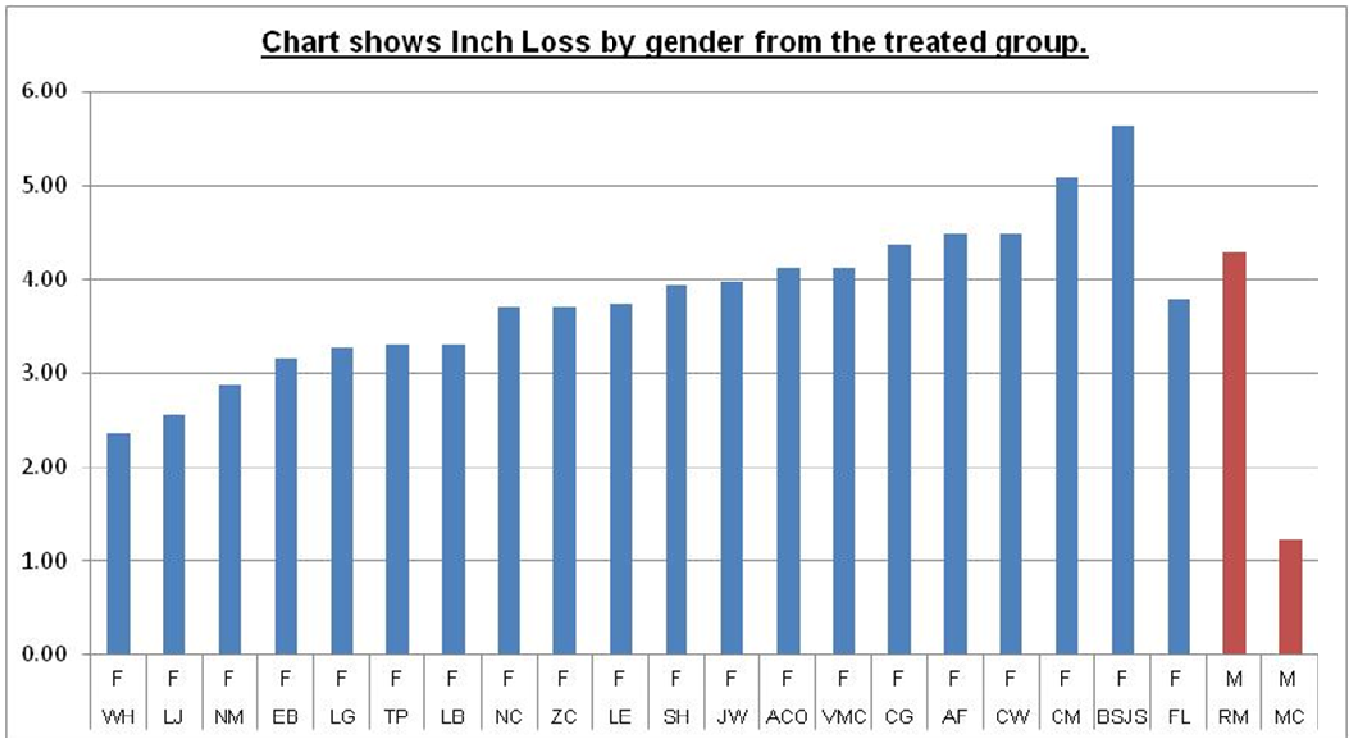
Placebo Ages:		
Subject Initials:	Inch Loss:	Age:
LL	-1.02	33
KD	-0.98	40
JB	-0.55	31
CMR	0	54
NH	0.28	76
JS	0.71	57
AB	0.79	47
LG	0.94	25
CM	0.98	48
MH	1.06	76
PO	1.06	49
SP	1.14	30
SH	1.3	24

Treated Ages:		
Subject Initials:	Inch Loss:	Age:
EB	3.15	20
ACO	4.13	20
NM	2.87	22
ZC	3.70	26
MC	1.22	27
CW	4.49	27
TP	3.31	28
LB	3.31	29
LG	3.27	31
SH	3.94	31
CG	4.37	31
LJ	2.56	34
VMC	4.13	34
BSJS	5.63	36
WH	2.36	39
CM	5.08	41
AF	4.49	42
NC	3.70	43
RM	4.29	43
FL	3.78	47
JW	3.98	52
LE	3.74	55

Chart showing the subject age groups as a percentage of the study.

- In 20's
- In 30's
- In 40's
- In 50's
- Over 70

2. Treatment Data and Charts

Chart shows Inch Loss by gender from the treated group.

There does not appear to be any trend relating to the results and the subject's gender.

Treated Gender:		
Subject Initials:	Gender:	Inch Loss:
WH	F	2.36
LJ	F	2.56
NM	F	2.87
EB	F	3.15
LG	F	3.27
TP	F	3.31
LB	F	3.31
NC	F	3.70
ZC	F	3.70
LE	F	3.74
SH	F	3.94
JW	F	3.98
ACO	F	4.13
VMC	F	4.13
CG	F	4.37
AF	F	4.49
CW	F	4.49
CM	F	5.08
BSJS	F	5.63
FL	F	3.78
RM	M	4.29
MC	M	1.22

3. Statistical analysis.

To test for randomisation bias, the Fishers Exact Test (2-sided) was used. The *p-value* was determined to be <0.05, assuming a null hypothesis. Randomisation is determined to be better than 95%. Therefore randomisation was achieved.

Limit on Control Success for Statistical Significance (Fisher's Exact,
2-sided) for Given Sample Size and Success Rate among the Treated

# Treated	# Placebos	Number of Successes among Treated	Allowable Successes among Placebos	Number of Successes among Placebos	
21	11	20 (>95%)	≤ 5	0	(ACTUAL)
20	10	18 (90%)	≤ 5		(EXAMPLE)
20	10	16 (80%)	≤ 4		(EXAMPLE)
20	10	14 (70%)	≤ 3		(EXAMPLE)

CELL MAP:

A	B
C	D

	loss > 1.6"	*loss < 1.6"*	margins		**RESULTS:**
Treated	20	1	21.00	A&B!	51090942171709400000.0
Placebo	0	11	11.00	C&D!	39916800.00
margins	20.00	12.00	32.00	A&C!	24329020081766400000.00
				B&D!	479001600.00
				N!	2.63131E+35
				Formula:	2.37663E+54
					2.55536E+61

p-value <0.05   **Probability:**   **9.30056E-08**

4.   Conclusions.

The criteria for success in this study was that at least 80% of the treated study subjects would achieve a lost of at least 1.6 inches around their waist (measured at the iliac crest, parallel to the floor) over 8 treatments in a 4 week period, while no more than 40% of the placebo group would achieve at least 1.6 inches around the waist.

The original plan was to use 20 participants for the treated group and 10 participants for the placebo (sham) group. In order to ensure that these numbers of participants were still active at the end of the 4-week study, a total of 35 participants were recruited. 22 of participants were randomly chosen to be members of the treated group and 13 participants were chosen to be members of the placebo group.

At the end of the 4 weeks, only 32 persons completed the study; 21 in the treated group and 11 in the placebo group. Rather than randomly reducing the number of participants from 32 to 30, the actual number of participants who finished all eight treatments in the 4 week period were used to consider success or failure of the study.

In the table shown below, 21 participants in the treated group completed all treatments. Of the 21 treated, 20 lost more than 1.6 inches around the waist and 1 did not. Therefore, 95.24% of the treated group lost >1.6 inches around the waist.

Of the 11 participants in the placebo group, no one lost 1.6 inches or more from around the waist.

# Treated	# Placebos	Number of Successes among Treated	Allowable Successes among Placebos	Number of Successes among Placebos
21	11	20 (>95%)	≤ 5	0

Based on the data gathered, within all constraints set forth in the prospective clinical study protocol, the Laser Lipo Strawberry and Cream laser system has fulfilled the criteria for success within the parameters of this study.

In addition, it is important to note that there were no adverse reactions experienced by any of the placebo or treated subjects.