



PIROCTONE OLAMINE SHAMPOO *
vs A COMPETITOR'S SHAMPOO **: **
ANTI-DANDRUFF ACTIVITY
USING THE HALF-HEAD TECHNIQUE

LSR Report No. : 81/SCH002/024

We, the undersigned, hereby declare that the report following constitutes a true and faithful account of the procedures adopted, and the results obtained, in the performance of this study.

P.C. Rofe, Ph.D.
(Associate Director)

.....

J. Fincham, Ph.D.
(Human Studies Manager)

.....

* Containing 0.75 % Piroctone Olamine

** Containing 1.0 % Climbazole



PIROCTONE OLAMINE SHAMPOO *
vs A COMPETITOR'S SHAMPOO :
ANTI-DANDRUFF ACTIVITY
USING THE HALF-HEAD TECHNIQUE

LSR Report No. : 81/SCH002/024

We, the undersigned, hereby declare that the report following constitutes a true and faithful account of the procedures adopted, and the results obtained, in the performance of this study.

P.C. Rofe, Ph.D.
(Associate Director)

.....

J. Fincham, Ph.D.
(Human Studies Manager)

.....

* Containing 1 % Climbazole

C O N T E N T S

	<u>Page</u>
SUMMARY	1
INTRODUCTION	2
METHODS	3
RESULTS AND DISCUSSION	6
 <u>FIGURE</u>	
1. Mean half-head values for area of dandruff x severity and area only, in 32 subjects before and after receiving weekly treatments with Piroctone Olamine and a competitor's shampoo	10
 <u>TABLES</u>	
1. Significance of differences between initial mean scores (area x severity) for each product and those at 14, 28 and 42 days, and comparison of means at each stage ...	11
2. Significance of differences between initial mean scores (area only) for each product and those at 14, 28 and 42 days, and comparison of means at each stage	12
3. Group mean scores for greasiness	13
 <u>APPENDICES</u>	
1. Composition of panel by age and sex	14
2. Example of completed dandruff grading form	15
3. Half-head scores left (L) or right (R) for dandruff before and during treatment with Piroctone Olamine shampoo (e) or a competitor's shampoo (d) assessed according to an arbitrary scale (area x severity)	16
4. Half-head scores left (L) or right (R) for dandruff before and during treatment with Piroctone Olamine shampoo (e) or a competitor's shampoo (d) assessed according to an arbitrary scale (area only)	17
5. Half-head objective assessment left (L) or right (R) for greasiness before and during treatment with Piroctone Olamine shampoo (e) or a competitor's shampoo (d) according to an arbitrary scale	18

C O N T E N T S - continued

	<u>Page</u>
<u>APPENDICES</u> - continued	
6. Types of dandruff for the two quadrants of the side of the head treated with Piroctone Olamine shampoo assessed according to an arbitrary scale; individual values for two groups of subjects	19
7. Half-head scores for sides of head treated with Piroctone Olamine shampoo in two groups of 12 and 20 subjects with differing types of dandruff, assessed according to an arbitrary scale; individual values and group means ...	20
8. Types of dandruff for the two quadrants of the side of the head treated with competitor's shampoo, assessed according to an arbitrary scale; individual values for two groups of subjects	21
9. Half-head scores for sides of head treated with competitor's shampoo in two groups of 11 and 21 subjects with differing types of dandruff, assessed according to an arbitrary scale; individual values and group means	22

S U M M A R Y

1. Thirty-two subjects with moderate or severe dandruff received Piroctone Olamine shampoo and a competitor's shampoo concurrently, one product to each half of the scalp, weekly for six weeks. After each application, the product was rinsed off and re-applied followed by further rinsing. Using indices based upon the area of the scalp affected, multiplied by the severity of dandruff, according to an arbitrary scale, dandruff was assessed on the day before treatment started and on treatment Days 14, 28 and 42.
2. Comparison of the mean dandruff scores (area x severity) obtained before the first treatment (Day -1) and seven days after the last treatment (Day 42), revealed a mean reduction of 51.4% associated with Piroctone Olamine, compared to a mean reduction of 44.2% associated with the competitor's shampoo. Both these reductions were highly significant ($p < 0.001$). On Days 14 and 28, compared with Day -1, Piroctone Olamine shampoo showed highly significant reductions ($p < 0.01$); the competitor's shampoo showed significant reductions ($p < 0.05$) on these two days.
3. Direct comparison showed that there were no significant differences between the mean dandruff reductions associated with the two treatments, at any stage of the trial.
4. Similar results were, in general, obtained when scores were derived from area of dandruff only. However, mean reductions for area of dandruff after two weeks (Day -1 scores less Day 14 scores) showed a higher significance for both shampoos than mean reductions derived from area x severity.
5. Both shampoos were associated with a slight increase in greasiness of the hair, but no difference between treatments was detected.
6. Piroctone Olamine appeared to be associated with an earlier improvement in loose dandruff than the competitor's shampoo, but no difference between treatments was apparent in relation to adhering dandruff.

I N T R O D U C T I O N

In a previous trial* the anti-dandruff efficacy of a shampoo containing Piroctone Olamine (Schwarzkopf) was tested against an inactive product by the half-head method over a period of six weeks, treatment being administered once weekly, in a salon.

The aim of the current trial, which was similar in design, was to test the relative anti-dandruff efficacy of the Piroctone Olamine shampoo (Schwarzkopf) and another competitor's shampoo.

* LSR Report No. 80/SCH001/134.

METHODS

1. Experimental design

Thirty-two subjects (21 women and 11 men) with moderate or severe dandruff used an inactive shampoo at home for two weeks. For the next six weeks they were treated weekly with Piroctone Olamine shampoo (Schwarzkopf) and a competitor's shampoo, one shampoo to each half of the head. Assessment of dandruff was made on the day before the first treatment (Day -1), and on Days 14, 28 and 42.

2. Selection of subjects

Seventy volunteers were examined to determine the type and extent of dandruff present. Volunteers undergoing medical treatment for a scalp condition, and those with visible inflammation of the scalp, were excluded from the trial. Thirty-nine volunteers with a dandruff score of at least 7 (area x severity) on each side of the head were issued with an inactive shampoo to use at home for 13 days.

On Day -1 they were again assessed. Thirty-four with moderate or severe dandruff were randomly allocated to two treatment groups such that the group mean dandruff scores (area x severity) and the numbers in the two groups were approximately equal. Seventeen volunteers received Piroctone Olamine on the right side of the head throughout the trial, and 17 received it on the left side. The inactive shampoo was applied to each head on the alternate side. Appendix 1 provides the age and sex of the 32 subjects who completed the trial.

3. Product coding and description

The inactive shampoo for use at home was supplied in 200 ml clear plastic bottles labelled as follows:

Shampoo c

Wet the hair and apply shampoo. Lather and rinse. Repeat the application, then rinse again.

Caution: Not to be taken internally.
Keep out of children's reach.
Avoid getting shampoo into eyes. If this happens, rinse eyes with water.

Distributed by: Life Science Research,
Stock, Essex.

The Piroctone Olamine and the competitor's shampoo for the treatment period were supplied in 200 ml clear plastic bottles, labelled "Shampoo mark e" and "Shampoo mark d" respectively.

Shampoo c was an opaque creamy bright blue liquid with a fresh perfume. Shampoo e was an opaque creamy turquoise-blue liquid with a similar, but milder, perfume. Shampoo d was a clear amber liquid with a sweet perfume.

4. Treatment

During the two weeks immediately preceding the study, subjects used the inactive shampoo at home *ad lib* for the first eight days. They were instructed not to wash their hair after Day -7.

During the six weeks of treatment, on Days 0, 7, 14, 21, 28 and 35, application of the shampoos to the scalp and washing of the hair was performed by three professional hairdressers, supervised at all times by Life Science Research staff. After parting the hair in the mid-line and securing the hair on one side with clips, the subject's head was positioned so that the back of the head was over a washbasin and tilted towards the side to be washed. Shampoo, 5 - 10 ml according to the length and thickness of the hair, was then applied directly to the scalp at several places by the hairdresser, and gently distributed with the tips of the fingers up to the parting. In view of the angle of the head, no difficulty was experienced in keeping the shampoo within the required area. Careful rinsing of the area with a warm water spray was followed by a further application of shampoo, followed by rinsing, as described above; finally, surplus water was taken up by gentle mopping with a towel.

The procedure was then repeated using the alternative product on the other side of the head.

5. Assessment of dandruff

The pre-treatment observations (Day -1) took place six days after washing the hair at home with the inactive shampoo.

During the treatment period, observations on all subjects were made seven days after the hair had been washed in the salon. On each occasion, the four quadrants of the scalp were separately assessed for dandruff in terms of the proportion of the scalp affected and severity, and scored according to the following criteria:

Area of quadrant affected:

Less than 10%	0
10 - 30%	1
30 - 50%	2
50 - 70%	3
70% or more	4

The area scores for the two quadrants on one side were added together. The maximum possible score for area for one side was therefore $4 \times 2 = 8$.

Severity :

Codes used on grading sheets
(see Appendix 2)

Small flakes resembling a coarse greyish-white powder	1	A
Intermediate	2	AB
Large flakes very loosely attached to the scalp and giving an irregular whitish surface	3	B
Intermediate	4	BC
Flakes apparently congealed together into yellowish plates adhering to the scalp, sometimes with evidence of exudate and erythema	5	C
Small flakes as "A" adhering to scalp as "C"	3	AC

For each quadrant, the score for area was multiplied by the score for severity. The scores for the two quadrants on one side were then added together. The maximum possible score for one side was therefore $(4 \times 5) \times 2 = 40$.

Observations were made by two examiners, Mrs. Ann Town and Mrs. Rita Slater, who were not aware of the particular treatment allocated to individual subjects.

6. Assessment of greasiness

At each dandruff assessment, greasiness of the hair was judged by the examiners according to the following scale:

Greasiness - seven days after washing hair

Very dry	0
Dry	1
Normal	2
Greasy	3
Very greasy	4

7. Location and dates of study

The study took place at Westcliff-on-Sea, Essex, England, from 15 October to 10 December 1980.

8. Statistical analysis

The significance of changes in mean dandruff scores within treatments, and of differences among such changes between treatments, was assessed by an analysis of variance appropriate to a paired design. Alan Whinney, F.I.S. was responsible for the statistical analysis.

RESULTS AND DISCUSSION

Individual dandruff assessments and group means are tabulated in Appendices 3 and 4 and displayed in Figure 1. Statistical examination of these data is summarised in Tables 1 and 2.

Of the 32 subjects who completed the trial, 11 women and four men received Piroctone Olamine shampoo on the left side of the head and the competitor's shampoo on the right side; ten women and seven men received the shampoos in the reverse order.

1. Anti-dandruff efficacy : scores for area x severity, maximum 40

(Figure 1; Table 1; Appendix 3)

The mean dandruff scores (area x severity) taken before the first treatment were 24.3 for the sides of the head to be treated with Piroctone Olamine, and 24.9 for those to be treated with the competitor's shampoo.

Piroctone Olamine (area x severity)

After six weeks treatment the mean dandruff score associated with Piroctone Olamine shampoo had decreased from 24.3 to 11.8, a reduction of 51.4% which was highly significant ($p < 0.001$). The reductions after two and four weeks treatment with Piroctone Olamine (9.1% reduction on Day 14; 23.5% reduction on Day 28) were also highly significant ($p < 0.01$).

Competitor's shampoo (area x severity)

After six weeks treatment the group mean dandruff level associated with the competitor's shampoo fell from 24.9 to 13.9, a reduction of 44.2% which was highly significant ($p < 0.001$). However, after two and four weeks treatment the reductions of 4.8% and 18.1% reached only the 5.0% level of significance ($p < 0.05$).

Piroctone Olamine shampoo vs. the competitor's shampoo (area x severity)

Piroctone Olamine shampoo appeared to have a somewhat faster action than the competitor's shampoo. Of the total mean dandruff reduction seen at six weeks, about one-fifth had occurred after two weeks (compared with about one-tenth in the competitor's product), and nearly half after four weeks (compared with approximately two-fifths for the competitor).

However, a direct comparison of the changes in the mean scores from Day -1 values, associated with the two shampoos, failed to show a significant difference between the reduction associated with the Piroctone Olamine, and that observed with the competitor's shampoo, at any stage of the trial.

2. Anti-dandruff efficacy : scores for area only, maximum 8

(Figure 1; Table 2; Appendix 4)

The mean scores for area of dandruff only, taken before the first treatment, were 6.3 for the sides of the head to be treated with Piroctone Olamine, and 6.5 for the sides to be treated with the competitor's shampoo.

Piroctone Olamine (area only)

The mean dandruff score for area only, associated with Piroctone Olamine shampoo, was lowered from 6.3 at the start of the treatment to 3.3 after six weeks, a reduction of 47.6% which was highly significant ($p < 0.001$). Reductions after two weeks (11.1%, $p < 0.001$) and four weeks (15.9%, $p < 0.01$) were also highly significant.

Competitor's shampoo (area only)

The mean dandruff score for area only, associated with the competitor's shampoo, showed a reduction from 6.5 to 3.8 after six weeks treatment. This 41.5% reduction was highly significant ($p < 0.001$). A highly significant reduction in mean dandruff area also occurred after two weeks (6.2%, $p < 0.01$), but the larger variation in individual responses which took place after four weeks treatment meant that this 12.3% reduction only reached significance at the 5.0% level ($p < 0.05$).

Piroctone Olamine vs. competitor's shampoo (area only)

There were no significant differences between the changes in area of dandruff scores from Day -1 scores, associated with the two treatments.

3. Anti-dandruff efficacy : conclusions arising from the use of the severity component in scoring

(Appendices 6 - 9)

In a previous trial, we looked at the progress of dandruff on areas of the scalp grouped according to three severity types, as follows: those with predominantly loose fine dandruff (types A, AB); those with fine flakes starting to adhere, or large loose flakes (types AC, B); and those with predominantly adhering dandruff (types BC, C). An examination of the results on the current trial showed no subjects in the first of these groups, but we were able to examine the progress with Piroctone Olamine of 12 scalp areas which fell into the AC, B group, and the remaining 20 which were in the BC, C group (Appendices 6 and 7). The corresponding numbers for areas treated with the competitor's shampoo were 11 in the AC, B group and 21 in the BC, C group (Appendices 8 and 9).

In general, for both shampoos, those with looser, finer dandruff showed a greater percentage reduction after six weeks treatment, than those with adhering dandruff. This difference in response was particularly marked in the areas treated with Piroctone Olamine (74.7% reduction in the AC, B group compared with 42.6% reduction in the BC, C group).

The areas with predominantly adhering dandruff which were treated with the competitor's shampoo showed a similar response to that achieved with Piroctone Olamine, the final reduction being 40.5%.

The areas with looser, finer dandruff, treated with the competitor's shampoo, were more resistant to treatment in the early stages of the trial, particularly after four weeks, at which time they showed only a 1.6% mean reduction from Day -1 scores; however, they showed a marked improvement after six weeks, when the reduction was 54.2%. Finer, looser dandruff treated with Piroctone Olamine did not suffer from this apparent relapse at four weeks.

The proportions in each of the four groups who responded well, i.e. whose score (area x severity) fell below 7 after six weeks, were roughly similar for both treatments:

<u>Treatment</u>	<u>Group by type of dandruff</u>	<u>Number of areas of group</u>	<u>Number of areas scoring less than 7 after 6 weeks</u>	<u>% of group</u>
Piroctone Olamine	AB, B	12	8	66.7
	BC, C	20	5	25.0
Competitor's shampoo	AB, B	11	6	54.6
	BC, C	21	8	38.1

The proportion of subjects who showed resistance to treatment (i.e. whose dandruff score (area x severity) had increased after six weeks, or had fallen by less than 25%) was less in the Piroctone Olamine group than in the group receiving the competitor's shampoo.

<u>Treatment</u>	<u>Group by type of dandruff</u>	<u>Number of areas of group</u>	<u>Number of areas in which dandruff was reduced by less than 25% after 6 weeks</u>	<u>% of group</u>
Piroctone Olamine	AC, B	12	0	0.0
	BC, C	20	6	30.0
Competitor's shampoo	AC, B	11	2	18.2
	BC, C	21	10	47.6

Examination of the results according to type and severity of dandruff showed the effectiveness of the two shampoos to be approximately similar, but detected an earlier response to treatment with Piroctone Olamine in those with finer, looser dandruff.

3. Greasiness scores

(Table 3: Appendix 5)

Greasiness of the hair increased slightly, overall. The mean score for greasiness was 2.8 for both groups after six weeks treatment, compared with a mean of 2.3 before treatment began. However, no difference in the effect of the two shampoos on greasiness was detected in any individual at any assessment during the trial.

4. Subject number 13

Subject number 13, a male aged 58, was asked to leave the trial after three weeks treatment because he had developed erythema, with encrustation and exudate, on areas of the scalp near the hair line on the forehead, and behind the ears. He was advised to seek medical attention. He had a history of psoriasis on the chest and back in his youth, but had since been free of this.

In 1979 he took part in an anti-dandruff trial in which he was successfully treated with a shampoo containing zinc pyrithione.

Earlier in 1980 he had been screened for a further anti-dandruff trial, but had been rejected because his dandruff was so mild. He had used Head and Shoulders, Silvikrin and Vaseline anti-dandruff shampoos in the past, with no problems. He had noticed that scalp irritation built up after using V05.

This subject was very satisfied with the treatment he received on the trial, and with the shampoos, and would have liked to continue.

FIGURE 1

Mean half-head values for area of dandruff x severity and area only, in 32 subjects before and after receiving weekly treatments with Piroctone Olamine shampoo and a competitor's shampoo

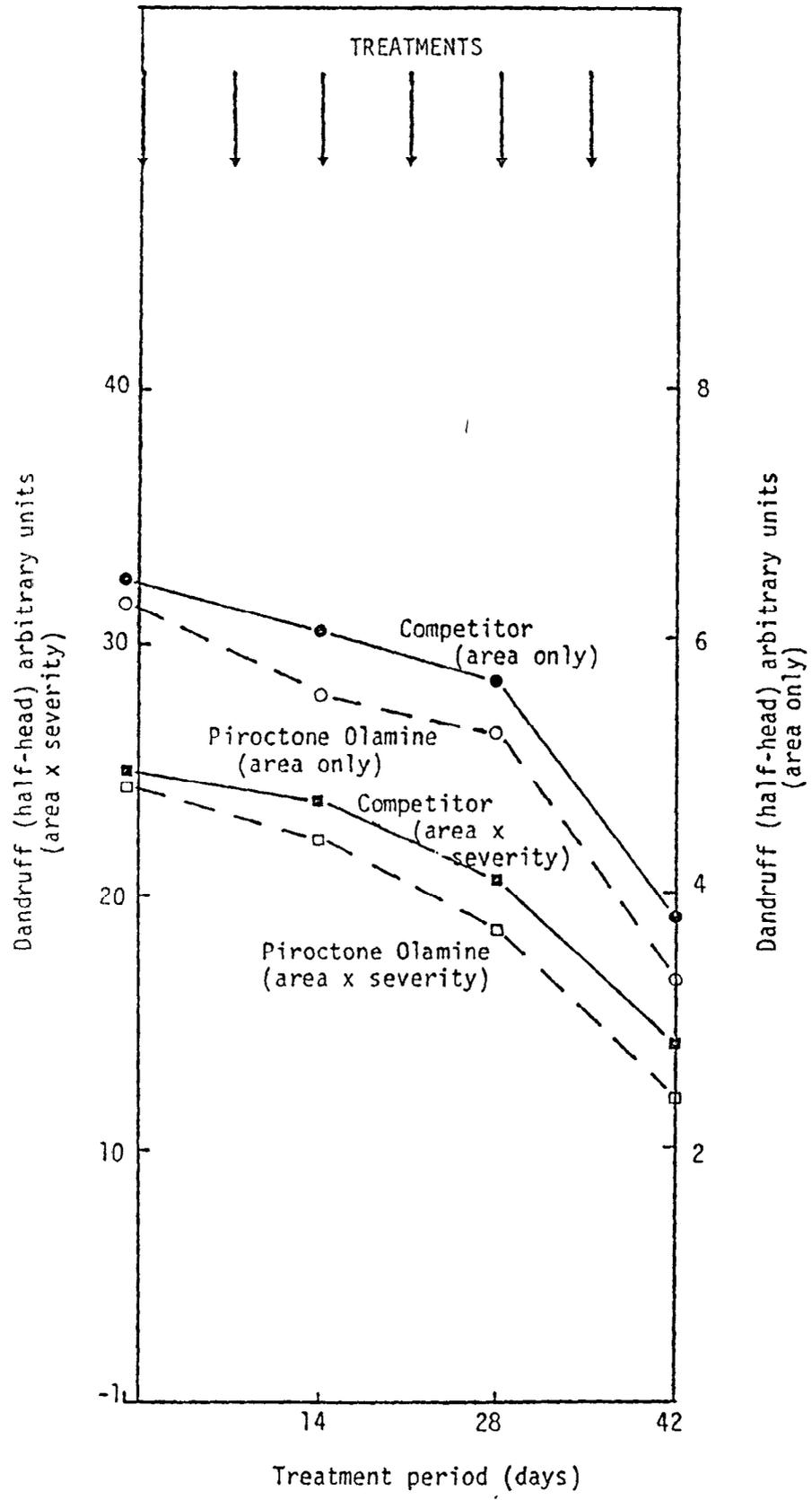


TABLE 1

Significance of differences between initial mean scores (area x severity) for each product and those at 14, 28 and 42 days, and comparison of means at each stage

	Days since start of half-head treatment															
	Day -1				Day 14				Day 28				Day 42			
	d	e	Δ	p	d	e	Δ	p	d	e	Δ	p	d	e	Δ	p
Mean score	24.9	24.3			23.7	22.1			20.4	18.6			13.9	11.8		
Initial score minus current score					1.2	2.2	1.0	NS	4.5	5.7	1.2	NS	11.0	12.5	1.5	NS
% decrease					4.8	9.1			18.1	23.5			44.2	51.4		
p					*	**			*	**			***	***		

NS Not significant
 * p < 0.05.
 ** p < 0.01.
 *** p < 0.001.

TABLE 2

Significance of differences between initial mean scores (area only)
 for each product and those at 14, 28 and 42 days, and comparison of means at each stage

	Days since start of half-head treatment															
	Day -1				Day 14				Day 28				Day 42			
	d	e	Δ	p	d	e	Δ	p	d	e	Δ	p	d	e	Δ	p
Mean score	6.5	6.3			6.1	5.6			5.7	5.3			3.8	3.3		
Initial score minus current score					0.4	0.7	0.3	NS	0.8	1.0	0.2	NS	2.7	3.0	0.3	NS
% decrease					6.2	11.1			12.3	15.9			41.5	47.6		
p					**	***			*	**			***	***		

NS Not significant
 * p < 0.05.
 ** p < 0.01.
 *** p < 0.001.

TABLE 3

Group mean scores for greasiness (0 - 4 scale)

Treatment	After 2 weeks inactive shampoo	After 2 weeks treatment	Mean increase since start of treatment	After 4 weeks treatment	Mean increase since start of treatment	After 6 weeks treatment	Mean increase since start of treatment
Piroctone Olamine	2.3	2.4	0.1	2.7	0.4	2.8	0.5
Competitor's shampoo	2.3	2.4	0.1	2.7	0.4	2.8	0.5

APPENDIX 1

Composition of panel by age and sex

Subject number	Age	Sex
1	37	Female
2	37	Female
3	66	Male
4	43	Female
5	51	Female
6	25	Female
7	29	Female
8	65	Female
9	66	Male
10	38	Female
11	67	Male
12	42	Male
14	69	Female
15	36	Male
16	57	Female
17	31	Female
18	63	Male
19	45	Female
20	45	Male
21	36	Female
22	37	Female
23	50	Female
24	62	Male
25	73	Male
26	47	Female
27	56	Female
28	35	Female
29	47	Female
31	53	Female
32	74	Male
33	46	Male
34	56	Female

APPENDIX 2 - Example of completed dandruff grading form

DANDRUFF GRADING FORM
(HALF-HEAD)

Trial Code: _____

Subject No. _____

Centre: _____

Allocation No. _____

Miss _____
Mrs. _____
Mr. _____

Initials: _____

Address: _____

Telephone No. Home: _____

Work: _____

Age: _____

Exam date	Days since last wash	Left greasiness	Left front	Left back	Total (area x severity)	Total (area only)	Right greasiness	Right front	Right back	Total (area x severity)	Total (area only)
28.10.80	6	2	4BC	4AC	28	8	2	4AC	4BC	28	8
12.11.80	7	2	4BC	4BC	32	8	2	4AC	4BC	28	8
11.11.80	7	2	4C	4C	40	8	2	4C	4AC	32	8
10.12.80	7	2	3AC	3AC	18	6	2	3AC	3BC	21	6

APPENDIX 3

Half-head scores left (L) or right (R) for dandruff before and during treatment with Piroctone Olamine shampoo (e) or a competitor's shampoo (d) assessed according to an arbitrary scale (area x severity, see text)

Subject number and sex	After 13 days on inactive (i.e. Day -1)		Days since start of half-head treatment					
			14		28		42	
	L	R	d L	e R	d L	e R	d L	e R
1F	28	28	32	28	40	32	18	21
5F	18	18	15	15	8	7	3	2
9M	25	25	25	25	4	20	2	10
10F	20	14	15	14	20	21	15	9
16F	35	35	30	30	5	14	4	5
18M	32	32	28	28	28	28	28	28
19F	15	12	15	9	10	7	2	0
20M	28	24	28	23	19	9	15	13
21F	18	21	15	15	10	21	3	2
26F	24	20	12	7	6	4	4	4
27F	21	21	21	28	32	24	18	9
29F	24	18	15	18	15	18	12	12
31F	24	24	32	32	32	32	8	18
33M	28	32	28	32	32	32	24	24
34F	21	21	15	16	24	24	24	21
	R	L	R	L	R	L	R	L
2F	20	25	24	17	22	11	4	2
3M	40	35	40	32	6	12	7	8
4F	32	32	32	32	32	32	32	25
6F	25	21	21	20	24	10	6	0
7F	25	16	25	14	24	14	28	0
8F	30	30	30	30	16	8	4	0
11M	32	28	32	28	36	36	31	32
12M	22	28	22	28	24	14	17	18
14F	32	36	32	36	40	40	40	40
15M	16	12	20	9	20	11	24	8
17F	32	36	32	36	32	36	32	24
22F	32	32	28	28	13	18	6	0
23F	28	28	24	20	6	3	3	2
24M	10	12	13	6	21	10	6	0
25M	20	24	20	24	21	32	21	32
28F	15	12	12	3	12	3	0	0
32M	25	25	25	25	18	12	4	8
Mean	24.9	24.3	23.7	22.1	20.4	18.6	13.9	11.8

APPENDIX 4

Half-head scores left (L) or right (R) for dandruff before and during treatment with Piroctone Olamine shampoo (e) or a competitor's shampoo (d) assessed according to an arbitrary scale (area only, see text)

Subject number and sex	After 13 days on inactive (i.e. Day -1)		Days since start of half-head treatment					
	L	R	14		28		42	
			d L	e R	d L	e R	d L	e R
1F	8	8	8	8	8	8	6	6
5F	6	6	5	5	4	5	2	1
9M	5	5	5	5	1	4	1	3
10F	8	6	6	6	8	7	5	3
16F	7	7	6	6	2	4	1	2
18M	8	8	7	7	7	7	7	7
19F	5	4	5	3	5	3	1	0
20M	6	5	6	5	4	3	3	3
21F	6	7	5	5	4	7	1	1
26F	6	5	3	2	3	2	2	2
27F	7	7	6	7	8	8	6	3
29F	6	6	5	6	5	6	4	4
31F	8	8	8	8	8	8	2	6
33M	7	8	7	8	8	8	6	6
34F	5	5	5	4	6	6	6	5
	R	L	R	L	R	L	R	L
2F	6	7	6	5	6	4	1	1
3M	8	7	8	7	2	3	2	2
4F	8	8	8	8	8	8	8	7
6F	7	7	6	5	8	5	2	0
7F	7	5	7	4	8	5	7	0
8F	6	6	6	6	4	3	1	0
11M	8	7	8	7	8	8	7	7
12M	7	7	7	7	6	4	5	5
14F	8	8	8	8	8	8	8	8
15M	4	3	5	3	5	4	6	4
17F	8	8	8	8	8	8	8	8
22F	8	8	7	7	5	6	3	0
23F	7	7	6	5	3	1	1	1
24M	4	4	4	2	7	4	2	0
25M	5	6	5	6	7	8	6	8
28F	5	4	4	1	4	1	0	0
32M	5	5	5	5	4	3	1	2
Mean	6.5	6.3	6.1	5.6	5.7	5.3	3.8	3.3

APPENDIX 5

Half-head objective assessment left (L) or right (R) for greasiness before and during treatment with Piroctone Olamine shampoo (e) or a competitor's shampoo (d) according to an arbitrary scale (see text)

Subject number and sex	After 13 days on inactive (i.e. Day -1)		Days since start of half-head treatment					
	L	R	14		28		42	
			d L	e R	d L	e R	d L	e R
1F	2	2	2	2	2	2	2	2
5F	2	2	2	2	3	3	4	4
9M	2	2	3	3	4	4	4	4
10F	3	3	3	3	4	4	4	4
16F	2	2	2	2	3	3	3	3
18M	3	3	3	3	3	3	3	3
19F	2	2	2	2	2	2	2	2
20M	1	1	1	1	1	1	1	1
21F	3	3	2	2	2	2	3	3
26F	3	3	3	3	3	3	3	3
27F	2	2	2	2	2	2	2	2
29F	2	2	2	2	2	2	3	3
31F	2	2	2	2	2	2	2	2
33M	2	2	2	2	2	2	3	3
34F	2	2	2	2	2	2	2	2
	R	L	R	L	R	L	R	L
2F	3	3	3	3	3	3	3	3
3M	2	2	2	2	2	2	2	2
4F	1	1	1	1	2	2	2	2
6F	2	2	2	2	3	3	3	3
7F	2	2	2	2	2	2	2	2
8F	1	1	2	2	2	2	2	2
11M	3	3	3	3	1	1	1	1
12M	2	2	1	1	2	2	2	2
14F	1	1	2	2	2	2	2	2
15M	3	3	3	3	3	3	4	4
17F	3	3	3	3	3	3	3	3
22F	3	3	3	3	4	4	4	4
23F	2	2	2	2	4	4	4	4
24M	3	3	3	3	4	4	4	4
25M	2	2	3	3	3	3	3	3
28F	4	4	4	4	4	4	4	4
32M	2	2	4	4	4	4	4	4
Mean	2.3	2.3	2.4	2.4	2.7	2.7	2.8	2.8

APPENDIX G

Types of dandruff for the two quadrants of the side of the head treated with Piroctone Olamine shampoo, assessed according to an arbitrary scale (see text); individual values for two groups of subjects

Group 2 (12 subjects) (Type AC, B)									Group 3 (20 subjects) (Type BC, C)								
Subject number and sex	After 2 weeks inactive		Treatment days						Subject number and sex	After 2 weeks inactive		Treatment days					
	Back quadrant	Front quadrant	14		28		42			Back quadrant	Front quadrant	14		28		42	
			Back quadrant	Front quadrant	Back quadrant	Front quadrant	Back quadrant	Front quadrant				Back quadrant	Front quadrant	Back quadrant	Front quadrant	Back quadrant	Front quadrant
2F	AC	BC	AC	BC	AC	AB	AB	AB	1F	BC	AC	BC	AC	AC	C	BC	AC
5F	AC	AC	AC	AC	A	AB	AB	AB	3M	C	C	BC	C	BC	BC	BC	BC
6F	AC	AC	BC	BC	AB	AB	AC	-	4F	BC	BC	BC	BC	BC	BC	BC	B
7F	BC	AC	BC	AC	AC	AB	AB	-	8F	C	C	C	C	B	AB	B	AB
10F	AB	AC	AB	AC	AC	AC	AC	AC	9M	C	C	C	C	C	C	AC	BC
19F	AC	AC	AC	AC	A	AC	AB	AB	11M	BC	BC	BC	BC	BC	C	BC	C
21F	AC	AC	AC	AC	B	AC	AB	AC	12M	BC	BC	BC	BC	BC	B	BC	B
24M	A	B	A	B	AB	B	B	B	14F	BC	C	BC	C	C	C	C	C
27F	AC	AC	BC	BC	AC	AC	AC	AC	15M	BC	BC	B	B	B	AB	AB	B
28F	B	B	B	B	AB	B	A	-	16F	C	C	C	C	AC	C	AB	AC
29F	AC	AC	AC	AC	AC	AC	AC	AC	17F	BC	C	BC	C	BC	C	B	B
31F	AC	AC	BC	BC	BC	BC	AC	AC	18M	BC	BC	BC	BC	BC	BC	BC	BC
									20M	BC	C	BC	C	AC	AC	AC	C
									22F	BC	BC	BC	BC	B	B	B	-
									23F	BC	BC	BC	BC	B	B	AB	AC
									25M	BC	BC	BC	BC	BC	BC	BC	BC
									26F	BC	BC	BC	B	AB	AB	AB	AB
									32M	C	C	C	C	BC	AC	BC	AC
									33M	BC	BC	BC	BC	BC	BC	BC	BC
									34F	AC	C	AC	C	AC	C	AC	C

APPENDIX 7

Half-head scores (area x severity) for sides of head treated with Piroctone Olamine shampoo in two groups of 12 and 20 subjects with differing types of dandruff, assessed according to an arbitrary scale (see text); individual values and group means

Group 2 (12 subjects) (Type AC, B)					Group 3 (20 subjects) (Type BC, C)				
Subject number and sex	After 2 weeks inactive	Treatment days			Subject number and sex	After 2 weeks inactive	Treatment days		
		14	28	42			14	28	42
2F	25	17	11	2	1F	28	28	32	21
5F	18	15	7	2	3M	35	32	12	8
6F	21	20	10	0	4F	32	32	32	25
7F	16	14	14	0	8F	30	30	8	0
10F	14	14	21	9	9M	25	25	20	10
19F	12	9	7	0	11M	28	28	36	32
21F	21	15	21	2	12M	28	28	14	18
24M	12	6	10	0	14F	36	36	40	40
27F	21	28	24	9	15M	12	9	11	8
28F	12	3	3	0	16F	35	30	14	5
29F	18	18	18	12	17F	36	36	36	24
31F	24	32	32	18	18M	32	28	28	28
					20M	24	23	9	13
					22F	32	28	18	0
					23F	28	20	3	2
					25M	24	24	32	32
					26F	20	7	4	4
					32M	25	25	12	8
					33M	32	32	32	24
					34F	21	16	24	21
Mean	17.8	15.9	14.8	4.5		28.2	25.9	20.9	16.2
Δ		1.9	3.0	13.3			2.3	7.3	12.0
% reduction		10.7	16.9	74.7			8.2	25.9	42.6

APPENDIX 8

Types of dandruff for the two quadrants of the side of the head treated with competitor's shampoo, assessed according to an arbitrary scale (see text); individual values for two groups of subjects

Subject number and sex	Group 2 (11 subjects) (Type AC, B)								Group 3 (21 subjects) (Type BC, C)								
	After 2 weeks inactive		Treatment days						Subject number and sex	After 2 weeks inactive		Treatment days					
			14		28		42					14		28		42	
	Back quadrant	Front quadrant	Back quadrant	Front quadrant	Back quadrant	Front quadrant	Back quadrant	Front quadrant	Back quadrant	Front quadrant	Back quadrant	Front quadrant	Back quadrant	Front quadrant	Back quadrant	Front quadrant	
5F	AC	AC	AC	AC	AB	AB	A	AB	1F	AC	BC	BC	BC	C	C	AC	AC
6F	AC	BC	AC	BC	B	B	BC	AB	2F	AC	BC	BC	BC	BC	AC	BC	BC
10F	AB	AC	AB	AC	AC	AB	AC	AC	3M	C	C	C	C	AC	AC	BC	AC
19F	AC	AC	AC	AC	AB	AB	AB	AB	4F	BC	BC	BC	BC	BC	BC	BC	BC
21F	AC	AC	AC	AC	B	AB	AC	-	7F	AC	BC	AC	BC	AC	AC	BC	BC
24M	A	B	A	BC	AC	AC	AC	AC	8F	C	C	C	C	BC	BC	BC	BC
27F	AC	AC	BC	AC	BC	BC	B	AC	9M	C	C	C	C	BC	B	AB	AB
28F	B	B	B	B	B	B	B	B	11M	BC	BC	BC	BC	BC	C	BC	C
29F	AC	C	AC	AC	AC	AC	AC	AC	12M	AB	BC	AB	BC	BC	BC	BC	B
31F	AC	AC	BC	BC	BC	BC	BC	BC	14F	BC	BC	BC	BC	C	C	C	C
34F	AC	C	AC	AC	AC	C	AC	C	15M	BC	BC	BC	BC	BC	BC	BC	BC
									16F	C	C	C	C	AB	AC	BC	BC
									17F	BC	BC	BC	BC	BC	BC	BC	BC
									18M	BC	BC	BC	BC	BC	BC	BC	BC
									20M	BC	C	BC	C	BC	C	AC	C
									22F	BC	BC	BC	BC	AB	B	AB	AB
									23F	BC	BC	BC	BC	AB	AB	AC	AB
									25M	BC	BC	BC	BC	B	B	B	BC
									26F	BC	BC	BC	BC	AB	AB	AB	AB
									32M	C	C	C	C	C	AC	BC	AB
									33M	BC	BC	BC	BC	BC	BC	BC	BC

APPENDIX 9

Half-head scores (area x severity) for sides of head treated with competitor's shampoo in two groups of 11 and 21 subjects with differing types of dandruff, assessed according to an arbitrary scale (see text); individual values and group means

Group 2 (11 subjects) (Type AC, B)					Group 3 (21 subjects) (Type BC, C)				
Subject number and sex	After 2 weeks inactive	Treatment days			Subject number and sex	After 2 weeks inactive	Treatment days		
		14	28	42			14	28	42
5F	18	15	8	3	1F	28	32	40	18
6F	25	21	24	6	2F	20	24	22	4
10F	20	15	20	15	3M	40	40	6	7
19F	15	15	10	2	4F	32	32	32	32
21F	18	15	10	3	7F	25	25	24	28
24M	10	13	21	6	8F	30	30	16	4
27F	21	21	32	18	9M	25	25	4	2
28F	15	12	12	0	11M	32	32	36	31
29F	24	15	15	12	12M	22	22	24	17
31F	24	32	32	8	14F	32	32	40	40
34F	21	15	24	24	15M	16	20	20	24
					16F	35	30	5	4
					17F	32	32	32	32
					18M	32	28	28	28
					20M	28	28	19	15
					22F	32	28	13	6
					23F	28	24	6	3
					25M	20	20	21	21
					26F	24	12	6	4
					32M	25	25	18	4
					33M	28	28	32	24
Mean	19.2	17.2	18.9	8.8		27.9	27.1	21.1	16.6
Δ		2.0	0.3	10.4			0.8	6.8	11.3
% reduction		10.4	1.6	54.2			2.9	24.4	40.5