



H.A.L.T. Healthy Alternative Lice Treatment Study

**A clinical study to test mechanism of action of a novel
non-pharmaceutical product for headlice**

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1. Objective

The objective of this clinical study was to evaluate the pediculicidal and ovicidal efficacy, per label instructions, of an up to 60-minute application of the H.A.L.T. Lice Treatment Kit product on healthy individuals ages 3 to 70 years old (inclusive) infested with head lice.

2. Background

Pediculosis capitis is defined as the presence of lice on the scalp, with nits (the eggs of *pediculus capitis* or head lice) attached to the hairs. Recently it has become a major nuisance in school children resulting in many lost school days and frustrated parents. Also, there have been many reports of lice resistance to the most commonly used permethrins and pyrethrums found in the over-the-counter (OTC) market place. Pesticidal active pediculicides have also recently come under increased public scrutiny, as concerned parents demand efficacy with no side effects for the patient or the environment. A safe and effective alternative to these current products is desirable. The H.A.L.T. product contains no active ingredients. Its mechanism of action is mechanical, killing solely by scratching and shredding lice and nits through mild natural abrasives, tearing the insect exoskeleton. In addition, scrubbing and loosening the egg sack from the affected hair shafts through repeated passes of applicator brush help complete the process. Both the “H.A.L.T. Treatment Gel” as well as the “H.A.L.T. Shampoo Removal Gel” are completely natural and contain no harsh or active ingredients, parabens or phthalates.

3. Methods

Location and Dates

The study took place at a community center in Homestead, FL on the following dates: October 10-11 (Day 1), October 17 (Day 8) and October 24 (day 15).

Participant Recruitment

MUJER staff contacted families that may have had members with lice, and invited them to come in for screening. This was done entirely by word of mouth with no advertising for recruitment. All participants were of Hispanic ethnicity. Twenty-three (88%) of the participants were children under 18 years of age, and three (12%) of the participants were adults. Table 1 below presents the age breakdown of participants.

Table 1. Participant ages (n=26)

Age	#	%
3-7 years	4	15%
8-12 years	10	38%
13-17 years	9	35%
Adults	3	12%
TOTAL	26	100%

Screening

Subjects were asked about their use of medication (prescription or over-the-counter) for the treatment of head lice over the two weeks prior to the study. Use of pediculicides in the 2 weeks prior to the study was an exclusion criterion. Subjects were required to have at least three live lice to be eligible for enrollment into study. Demographic data (age, gender, race/ethnicity) were collected and documented on the subject's Case Report Form. Hair characteristics (length, texture, curliness) were also recorded (See Table 2). Table 3 reports the severity of infestation of participants at baseline.

Table 2. Participant hair characteristics

Hair texture	#	%	Hair curliness	#	%	Hair length	#	%
Fine	25	96%	Straight	17	65%	Short (< 5 in)	5	19%
Average	1	4%	Wavy	7	27%	Medium (5-10 in)	7	27%
Coarse	0	0	Curly	2	8%	long (10+ in)	14	54%
Total	26	100%	Total	26	100%	Total	26	100%

Table 3. Live lice and viable nits present at baseline

VIABLE NITS	Frequency	Percent
Mild (1-10)	9	36%
Moderate (10-50)	12	45%
Severe (50+)	5	18%
Total	26	100%

LIVE LICE	Frequency	Percent
Mild (1-5)	21	82%
Moderate (6-10)	4	15%
Severe (11-20)	1	3%
Total	26	100%

Informed consent

All adult subjects and minor subjects with legal guardians were provided an informed consent document. Each subject provided consent including assent signature lines for the minor subject (age 6 to 17) and parent/legal guardian signature lines. This document explained the purpose of the study, and allowed the investigator/designee to touch the subject and evaluate the subject for the presence of lice.

All subjects' parents/legal guardians had the study procedures and requirements, which were reviewed and approved by a licensed Institutional Review Board, (IntegReview IRB, Austin, TX.), fully explained to them and each was given the opportunity to ask questions. Subjects were not entered into the study without being fully informed or without comprehending what was required by their participation in the study. The voluntary nature of their participation was also made known, as were the risks and benefits of their participation. Consent and assent were provided in the participants' preferred Language (English or Spanish).

Treatment Procedure

The test product carton, “H.A.L.T. Lice Treatment Kit”, was composed of two 3.5 oz. plastic containers, one containing H.A.L.T. Treatment Gel and the other H.A.L.T. Shampoo Removal Gel. Also, the kit contains an instructional insert, magnifier, metal lice comb, and applicator brush. The application procedures were followed closely by project staff and were as follows:

1. Wet hair and apply the test H.A.L.T. Treatment Gel formulation to completely cover hair and scalp, followed by a 10-minute waiting period.
2. Using the applicator brush, (use only brush supplied in Kit), separate the hair into several smaller sections and vigorously brush the hair and scalp in each section, back and forth, in small strokes followed by a similar circular motion for up to 30 minutes. Only those with short hair, or medium length and fine hair, were vigorously brushed for 15 (very short hair) or 20 minutes.
3. Wait another 10 minutes to further emulsify nit glue and destabilize damaged adults.
4. Add more water to the hair and apply 3.5 oz H.A.L.T. Shampoo Removal Gel to the head and again, massage the scalp for 5 minutes, with the Applicator Brush, to clean lice, nits, and H.A.L.T. Gels from hair. Repeat this step as needed.
5. Apply neutral shampoo and brush vigorously down to the scalp, rinse shampoo, apply conditioner if needed for detangling, and rinse.

As the treatment process steps were completed, staff collected the rinse water. The rinse water was strained through white cotton towels to collect lice and lice parts to assess the extent of the infestation, and residual. After the final rinse, staff inspected the hair of the participants and used the fine-toothed metal nit comb, if lice or eggs were present. Participants’ hair was brushed and staff collected any additional lice for examination.

Participants returned for Visit 2 one week later (Day 8). All returning participants were screened for the presence of live lice. If no live lice were found, staff completed the case report form for the visit, including assessment for adverse events, and instructed participants to return in one week (Day 15). In case that live lice were found on Day 8, a second treatment with the test product was administered, following the same procedures as on Day 1. On Visit 3, (Day 15), participants were screened for the presence of live lice, and asked about adverse events. If live lice were found on Day 15, participants were given a rescue treatment (Nix) to be applied at home. All participants received their incentive payment in cash on Day 15.

Table 4 below presents the average number of minutes participants had the H.A.L.T. on the hair on both treatment days. Only 14 participants who had lice on Day 8 received a second treatment.

Table 4. Treatment application time in minutes

	N	Minimum	Maximum	Mean
First treatment	26	33	56	47.5
Second treatment	12	45	61	50.0

4. Results

Day 8

On the second visit (Day 8), 54% (n=14) of the participants were lice and nit free. The remaining 46% (12) were found to have lice. All but one had fewer than 5 visible live lice. Two thirds of the participants (69%) had no visible nits on Day 8. See Table 5. The 14 participants with live lice were treated a second time.

Table 5. Day 8 Results

Live lice	Frequency	Percent	Lice severity	Frequency	Percent
No	14	54%	Mild (1-5)	11	93%
Yes	12	46%	Moderate (6-10)	1	7%
Total	26	100%	Severe (10+)	0	0

Day 8 viable nits	Frequency	Percent	Day 8 nit severity	Frequency	Percent
No	18	69%	Mild (1-10)	1	13%
Yes	8	31%	Moderate (10-50)	5	62%
Total	26	100%	Severe (50+)	2	25%

Day 15

Two weeks after the first treatment, 89% (23) of the participants were lice free. Three participants (11.5%) were considered treatment failures because they had live lice found on Day 15 (See Table 6). It is likely the two participants with live lice and no nits on Day 15 were the result of a re-infestation.

Table 6. Day 15 Results

Outcome	Frequency	Percent
No lice, no nits	23	89%
No nits, live lice re-infestation	2	7%
Live lice, live nits	1	4%

Note: All lice and nit infestations were rated as mild on Day 15.

5. Conclusions

A clinical study was conducted with 26 participants to test the efficacy of the H.A.L.T. Healthy Alternative Lice Treatment Kit according to label instructions. There were no adverse events and participants tolerated the extended brushing very well. Table 7 summarizes the results.

Table 7. Final Results

Treatment Outcome	Frequency	Percent
Success	23	89%
Failure	3	11%
Total	26	100%

Two of the three treatment failures (7.7% of the total sample) were determined to be re-infestations, because they had been found to be lice free on Day 8, and did not receive a second treatment. If we exclude the re-infestations from the analysis, the **final efficacy is 95.8%** after two weeks, with a second treatment, if not cured on Day 8.

The results of this study support the following conclusions:

- 46% of participants were cured with 1 treatment
- An additional 42% of participants were cured with 2 treatments
- 54% pediculicidal efficacy at 1 week
- **89% pediculicidal and ovicidal efficacy at 2 weeks**
- **H.A.L.T. Healthy Alternative Lice Treatment kit is an effective Natural Lice eradication alternative to current treatment regimens on the market.**

APPENDICES

APPENDIX A. Photos

Participant treatment photographs removed from this public copy to protect participant privacy. The original report page showed study staff sectioning and brushing participants' hair with the applicator brush, with each participant brushed for up to 30 minutes tracked by individual timers.

Post treatment water/rinsate collection

Dead lice and pieces of crushed lice are visible in towels used to strain post-treatment rinse water.



APPENDIX B. Data

Count	Study number	Initials	Age	Gender (M,F)	Hair texture (1,2,3)	Hair curlyness (1,2,3)	Hair length (1,2,3)	mins of Tx duration - Day 1	viable eggs (yes,no)	if yes (1,2,3)	Live lice (yes,no)	if yes (1,2,3,4)	mins of Tx duration - Day 8
	Treatment	Initials redacted	sses										
1	3		11	M	1	1	1	54	NO		NO		
2	13		40	F	1	1	3	53	NO		NO		
3	8		39	F	1	1	2	45	NO		NO		
4	20		12	M	1	1	1	41	NO		NO		
5	21		31	F	1	3	3	52	NO		NO		
6	23		10	M	1	1	1	33	NO		NO		
7	24		13	F	1	2	3	50	NO		NO		
8	25		8	M	1	1	1	36	NO		NO		
9	26		10	F	1	2	3	38	NO		NO		
10	30		3	F	1	1	3	46	NO		NO	1	
11	33		3	F	1	1	3	50	NO		NO	0	
12	19		10	M	1	1	1	40	NO		NO		
13	4		16	F	1	1	3	55	NO		YES	1	45
14	7		4	F	1	1	3	51	NO		YES	1	46
15	18		8	F	1	2	2	34	NO		YES	1	50
16	29		11	F	1	2	2	54	NO		YES	1	50
17	1		15	F	1	1	2	52	YES	2	YES	1	43
18	2		13	F	1	1	3	33	YES	2	YES	1	61
19	5		13	F	1	1	3	51	YES	3	YES	1	45
20	12		14	F	1	2	3	48	YES	2	YES	1	53
21	27		9	F	1	1	2	53	YES	2	YES	1	56
22	28		13	F	1	1	2	55	YES	3	YES	2	47
23	35		13	f		2	2	2	53	YES	1	YES	1
	Treatment		es										
24	16	11	F	1	3	3	56	NO		NO			
25	31	17	F	1	1	3	50	NO		NO			
26	15	11	F	1	2	3	53	YES	2	YES	1	55	

Count	Study number	viable eggs (yes,no)	if yes (1,2,3)	Live lice (yes,no)	if yes (1,2,3,4)	Tx failure (Yes, No)	Comments
	Treatment						
1	3	no		no		no	Cured with 1 Tx
2	13	no		no		no	Cured with 1 Tx
3	8	no		no		no	Cured with 1 Tx
4	20	no		no		no	Cured with 1 Tx
5	21	no		no		no	Cured with 1 Tx
6	23	no		no		no	Cured with 1 Tx
7	24	no		no		no	Cured with 1 Tx
8	25	no		no		no	Cured with 1 Tx
9	26	no		no		no	Cured with 1 Tx
10	30	no		no		no	Cured with 1 Tx
11	33	no		no		no	Cured with 1 Tx
12	19	no		no		no	Cured with 1 Tx
13	4	no		no		no	Cured with 2 treatments
14	7	no		no		no	Cured with 2 treatments
15	18	no		no		no	Cured with 2 treatments
16	29	no		no		no	Cured with 2 treatments
17	1	no		no		no	Cured with 2 treatments
18	2	no		no		no	Cured with 2 treatments
19	5	no		no		no	Cured with 2 treatments
20	12	no		no		no	Cured with 2 treatments
21	27	no		no		no	Cured with 2 treatments
22	28	no		no		no	Cured with 2 treatments
23	35	no		no		no	Cured with 2 treatments
	Treatment						
24	16	yes	1	yes	1	yes	probably reinfestation
25	31	no		yes	1	yes	probably reinfestation
26	15	no		yes	1	yes	never lice free