

# Efficacy and safety of a new non-pesticide lice removal product.

Scanni G.\*, Bonifazi E.\*\*

\*Dermatologist, school physician, "ASL Ba 4, Distretto n. 1", Bari (Italy)

\*\*Pediatric Dermatology Unit, University of Bari, Bari (Italy)

## Summary

This report is aimed at verifying in an open "in vivo" study efficacy and safety of a new lice removal product (Paranix®, Chefaro Pharma Italy). The latter is a non-pesticide spray consisting of active natural agents, particularly coconut oil extract, anise essential oil and Ylang ylang oil. The efficacy and safety of Paranix® was compared to those ones of malathion (Aftir® gel, Biochimici PSN Italy) in 24 subjects, whose age ranged between 4 and 15 years. The latter were randomly treated with one of the two products. No subject showed clinically evident side effects attributable to the used product. 11/12 subjects of both groups did not show live lice or nits when combed four days after the first treatment. Two subjects in the group treated with Aftir and one subject in the group treated with Paranix complained about the odor of the product. In conclusion Paranix proved as effective as the strong lice removal product of the control group and devoid of side effects.

## Key words

Paranix, pediculosis capitis, non-pesticide lice removal product.

**P**ediculosis capitis probably exists from the appearance of humans on the earth, as shown by the recovery of dry lice and nits on the hair of Egyptian mummies (9). Although most civilizations and cultures considered pediculosis inappropriate, lice survived to all attempts of eradication, probably due to their capability of developing resistance against the various lice removal products. As the latter are not devoid of potential toxic effects, being more frequently pesticides, a need does exist for new lice removal products, possibly devoid of toxic effects.

Among the non-pesticide products a new all-natural product, consisting of coconut oil extract, anise essential oil, Ylang ylang oil and isopropyl alcohol, established itself on the market due to its efficacy and to the lack of toxic effects, as being a non-pesticide product. The product, which is on the market from 1995 in Israel with the name of Chick-Chack, from 1996 in the States with the name of Hair Clean 1-2-3 and from 2004 in the European Union,

included Italy, where it is on sale with the name of Paranix (Chefaro Pharma, Italy), proved (5) effective and safe, so that it is sold as medical device over the counter.

This study is aimed at testing even in Italy the safety and effectiveness of Paranix in comparison with one of the more popular product containing malathion (Aftir gel) for the treatment of pediculosis capitis.

## Material and methods

24 subjects, whose age ranged between 4 and 15 years, with an actual infestation due to *Pediculus humanus capitis*, thus with adult lice, nymphs or viable nits on the hair entered the study. The subjects underwent a control visit after 12 days. The subjects or their parents kept a daily diary, in which they reported the presence of lice and nits after combing with the specially provided metal nit picking comb already included in the packaging. One of the parents or

responsible relative of the minor, after having paid careful attention to the modalities and aim of the study, signed the form of informed consent.

*Exclusion criteria* were as follows:

1- subjects affected by scalp disorders of various type (psoriasis, ringworm, severe, febrile pyoderma, etc.);

2- subjects with actual febrile disorders requiring antibiotics;

3- subjects who in the week prior to the study took antibiotics or applied lice removal products;

4- subjects affected by disorders able to influence the response to lice removal products according to the responsible physicians;

5- subjects with confirmed hypersensitivity to malathion or to the essential oils of Paranix;

6- subjects who during the period of application of Paranix or Aftir used other lice removal products.

During the study other drugs could be used provided that they could not affect the results of the study according to the responsible physicians.

Subjects who entered the study were numbered according to the order of entry and received Paranix or Aftir according to the scheme as follows: 1, 4, 5, 7, 10, 11, 12, 15, 17, 19, 22, 24 received Paranix, whereas 2, 3, 6, 8, 9, 13, 14, 16, 18, 20, 21, 23 received Aftir. The subjects entering the study also received together with the lice removal product, a metal comb and a daily diary. They or their parents had to report on the diary the presence and number of viable or dead lice and nits every day during the period of study.

*How to use products.* With regard to the use of products the instructions as follows were given:

*Aftir gel:* apply 5 centimeters of gel or more than 5 according to the length of the hair all over the dry hair, making easier the contact of the product with the hair thanks to a normal comb. 10 minutes later wash the hair with a non medicated shampoo and then comb with the nit picking comb, given by the responsible physician because not present in the packaging. In the following days, once a day, comb daily with the

special comb, writing down on the diary the possible presence of viable or dead lice and nits and their number. Repeat the treatment after 7 days and go on with daily combing of the hair till the control visit.

*Paranix:* spray on the dry hair a quantity variable according to their length but anyway sufficient to wet completely all the hair. 15 minutes later wash the hair with a non medicated shampoo and then comb the hair with the given nit picking comb. In the following days, once a day, daily comb the hair with the appropriate comb, writing down on the diary the possible presence of viable or dead lice and nits and their number. Repeat the treatment a second time after 5 days and a third time after other 5 days, going on with the particular daily combing till the control visit.

*Recovery.* The subject was considered cured the day during which the examination of his/her parents and the particular daily combing did not put in evidence adult lice or nymphs or nits. Healing was in all cases confirmed on the control visit.

*Control visit.* 12 days after the first application of the lice removal product, the treated subjects, in order to confirm their recovery, were carefully examined by the responsible physician. The subjects also gave the physician their daily diary.

## Results

In the "paranix group" 11/12 subjects (92%) recovered within 3 days from the first treatment, whereas 1/12 subjects recovered within 12 days from the first treatment.

In the "aftir group" 11/12 subjects (92%) recovered within 4 days from the first treatment, whereas 1/12 subjects recovered within 8 days from the first treatment.

Particularly, in the "paranix group" 8/11 subjects recovered within 1 day, 2/11 within 2 days and 1/11 within 3 days from the first application of the product. In the "aftir group" 9/11 subjects recovered within 1 day, 1/11 within 2 days and 1/11 within 4 days from the first application of the product.

Two subjects in the group treated with Aftir and one subject in the group treated with Paranix complained about the odor of the product.

### Discussion

As above mentioned the subjects were conventionally considered as cured when they did not present adult lice or nymphs or nits during the appropriate combing with a nit picking comb, namely a comb able to keep also the nits. The analysis of the 24 treated cases first of all showed the good efficacy of both products used, because 92% of subjects recovered within 4 days from the first application of the product. This result could mean that in some cases the second application of the products is not necessary. The good result first of all depended of the effectiveness of the products used. However, we should also remember the role played by the nit picking comb, namely a comb with non-deformable teeth spaced out less than 0.3 mm away from each other. The latter makes the removal of viable nits as well of dead lice and nits easier. Such a comb is really useful in removing the viable nits, that are less responsive to treatment, due to the difficult penetration of all the products within the nit. On the other hand, the comb is less useful for lice, that are anyway more responsive to the treatment. This is why the nit picking comb should be always used in the treatment of pediculosis capitis and every product aimed at curing this infestation should include such a comb in its packaging. Its usage could be bothersome for subjects with long hair. In this case traumas can be reduced wetting previously the hair with water and treating them with a hairbrush able to untie possible knots of the hair.

2/12 subjects in the “paranix group” underlined in their daily diary the easier removal of the nits after the use of the product.

Both in the “paranix group” and in the “aftir group” 1/12 subjects recovered only after the second application of the product. This could be due to the difficult penetration of whatever lice removal product within the viable nit. Due to

this reason and to the well-known resistance that lice are able to develop against all the products (3, 10), especially lindane (1, 2, 4, 6, 7, 8, 11), all the lice removal products, included those ones initially advised in a single application, such as permethrin, should be repeated 5-10 days after the first application. The well documented resistance to the lice removal products also explains how a so bothersome infestation survived during several millennia (9), in spite of all the drugs used and finally justifies the need for new products in the treatment of pediculosis capitis.

From this point of view, Paranix is an innovative product, because it is very unlikely that lice could develop resistance against it. Paranix is really a mixture of natural oils and does not act with a chemical mechanism unlike other organic chlorine and phosphorus products and natural or synthetic (permethrin) pyrethins. For instance Aftir used in the actual study is an organic product of phosphorus, containing malathion, that inhibits in an irreversible way cholinesterase of the lice, blocking the conduction of nervous stimuli. On the other hand, Paranix is a mixture of natural oils acting with a physical mechanism, obstructing the respiratory ducts of lice and causing their immediate death by suffocation.

When comparing the side effects of the different lice removal products, one could not ignore that a mixture of natural oils is really less toxic for humans and environment than products containing organic chlorine or phosphorus. On the other hand, there is a contrast between the very careful attention paid by the media to the usage of pesticides in agriculture, with consequent always more restrictive regulations, and the silence regarding the usage of the same products in the treatment of human pediculosis. However, the actual study did not put in evidence any clinically evident side effect neither in the “aftir group” nor in the “paranix group”, showing that in the usage conditions also the products containing organic phosphorus are well tolerated. Two subjects in the group treated with Aftir and one subject in the group treated with Paranix complained about the odor of the product. This factor could influence the efficacy of the product. The subjects who complained about the odor of

the products were really also the subjects who recovered in longer time, favoring the hypothesis of an insufficient usage of the product. This is why the patients and their parents should be instructed in the usage of an amount of product able to completely wet the hair. This is also why a single packaging of product may be insufficient in some subjects with very long hair.

Finally, we should talk about prevention of pediculosis capitis. When an infestation with lice occurs in a family or social group, which is an almost obligatory event during the school period in all the developed countries, parents always ask teachers, physicians and druggists how to prevent the infestation in their children. The products actually on sale for the so-called "prevention" of pediculosis capitis are not effective and potentially toxic. The lack of toxicity of Paranix could promote its usage in the prevention of pediculosis. However, we believe that also a product seemingly devoid of side effects should not be used with the aim of prevention and we confirm that the only solution of this problem is an early diagnosis. The latter can be done with the daily use of a nit picking comb during the periods of infestation. This type of "prevention" should be done by parents and/or by an expert such as a social worker or a school

physician, when parents do not cooperate properly.

In conclusion this study, although in a small number of subjects, showed that a product containing only natural oils (Paranix ®) and thus probably devoid of side effects is as effective as one of the strongest lice removal product on sale (Aftir ®), that inhibits cholinesterase. In the usage conditions none of the products of the study was responsible for clinically evident side effects.

*Dr. Scanni was responsible for the clinical study, visited and controlled the patients. He also reviewed the report.*

*Dr. Bonifazi wrote the study protocol and the report.*

Address to:

Ernesto Bonifazi, MD

Pediatric Dermatology Unit

University of Bari - Policlinico

Piazza G. Cesare, 11 - 70124 Bari (Italy)

e-mail: ejpd@dermatologiapediatrica.com

### References

- 1) Blommers L., van Lennep M. - Head lice in the Netherlands: susceptibility for insecticides in field samples. *Entomol. Exp.* 23, 243-51, 1978.
- 2) Blommers L. - Insecticidal tests on immature head lice, *Pediculus capitis*: a new technique. *Med. Entomol.* 16, 82-3, 1979.
- 3) Downs A.M.R., Stafford K.A., Coles G.C. - Head lice: prevalence in schoolchildren and insecticide resistance. *Parasitol. Today* 15, 1-4, 1999.
- 4) Maunder J.W. - Resistance to organochlorine insecticides in head lice and trials using alternative compounds. *Med. Officer.* 125, 27-9, 1971.
- 5) Meinking T.L. - Infestations. *Curr. Probl. Dermatol.* 11, 73-120, 1999.
- 6) Meinking T.L., Entzel P., Villar M.E., et Al. - Comparative efficacy of treatments for pediculosis capitis infestations: Update 2000. *Arch. Dermatol.* 137, 287-92, 2001.
- 7) Meinking T.L., Serrano L., Hard B., et Al. - Comparative in vitro pediculicidal efficacy of treatments in a resistant head lice population in the United States. *Arch. Dermatol.* 138, 220-4, 2002.
- 8) Meinking T.L., Taplin D. - Infestations. In: Schachner L.A., Hansen R.C. eds. - *Pediatric Dermatology*. Mosby, 2003 Elsevier Limited.
- 9) Mumcuoglu K.Y., Zias J. - How the ancients deloused themselves. *Bibl. Archaeol. Rev.* XV(6):66, 1989.
- 10) Mumcuoglu K.Y., Hemingway J., Miller J., et Al. - Permethrin resistance in the head louse *Pediculus capitis* from Israel. *Med. Vet. Entomol.* 9, 427-32, 1995.
- 11) Taplin D., Meinking T.L., Castellero P.M., et Al. - Permethrin 1% Creme Rinse (NIX) for treatment of *Pediculus humanus var. capitis* infestation. *Pediatr. Dermatol.* 3, 344-8, 1986.