Safety and Tolerability of a Novel Malathion Formulation in Infants and Toddlers With Head Lice

This study is currently recruiting patients.

Verified by Taro Pharmaceuticals USA February 2006

Sponsored by:	Taro Pharmaceuticals USA
Information provided by:	Taro Pharmaceuticals USA
ClinicalTrials.gov Identifier:	NCT00291057

Purpose

In a previous phase II study, the safety and efficacy of a novel formulation of malathion 0.5% was evaluated in patients 2 years of age and older. Based on the results of that study, this formulation is currently in a phase III study for that population.

The current study will use blood markers and clinical evaluation to determine the safety and tolerability of this formulation when used in children 6-24 months of age.

Condition	Intervention	Phase
Head Lice	Drug: MALG (a novel formulation of malathion)	Phase II

MedlinePlus consumer health information

Study Type: Interventional
Study Design: Treatment, Non-Randomized, Open Label, Uncontrolled, Single Group Assignment, Safety Study

Official Title: Phase II, Multi-Center, Open-Label, Safety and Tolerance Study of a Novel Malathion Formulation in Infants and Toddlers With Pediculosis Capitis

Further study details as provided by Taro Pharmaceuticals USA:
Primary Outcomes: Change in cholinesterase level
Secondary Outcomes: Clinical evidence of cholinesterase inhibition; Local tolerability; Cure of head lice

14 days after last treatment
Expected Total Enrollment: 30

Study start: February 2006; Expected completion: July 2006
Last follow-up: May 2006; Data entry closure: June 2006

Eligibility

Ages Eligible for Study: 6 Months - 24 Months, Genders Eligible for Study: Both
Criteria

Inclusion Criteria:

- Confirmed active head lice infestation
- Parent of guardian must be able to apply treatment

Exclusion Criteria:

- Allergy to pediculicides or hair care products
- Scalp conditions other than head lice
- Previous head lice treatment within the past 4 weeks
- Current antibiotic treatment

Location and Contact Information

Please refer to this study by ClinicalTrials.gov identifier NCT00291057

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More Information

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