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

<table>
<thead>
<tr>
<th>Sponsored by:</th>
<th>Taro Pharmaceuticals USA</th>
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<tr>
<td>Information provided by:</td>
<td>Taro Pharmaceuticals USA</td>
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<tr>
<td>ClinicalTrials.gov Identifier:</td>
<td>NCT00291057</td>
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**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.

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<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
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<tr>
<td>Head Lice</td>
<td>Drug: MALG (a novel formulation of malathion)</td>
<td>Phase II</td>
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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
Clinical Trial: Safety and Tolerability of a Novel Malathion Formulation in Infants and Toddlers With 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

Medical Affairs Taro Pharmaceuticals (914) 345-9001 Ext. 6427 medical.affairs@taro.com

Arizona
Scottsdale, Arizona, 85251, United States; Recruiting
Robert A Lewine, MD, Principal Investigator

Florida
West Palm Beach, Florida, 33409, United States; Recruiting
John Goodman, MD, Principal Investigator
St. Petersburg, Florida, 33710, United States; Recruiting
Michael Brown, MD, Principal Investigator

Ohio
Clinical Trial: Safety and Tolerability of a Novel Malathion Formulation in Infants and Toddlers With Head Lice

Miamiville, Ohio, 45147, United States; Recruiting
Jan Fu, MD, PhD, Principal Investigator

Study chairs or principal investigators
John Goodman, MD, Principal Investigator, Hill Top Research
Robert A Lewine, MD, Principal Investigator, Hill Top Research
Michael Brown, MD, Principal Investigator, Hill Top Research
Jan Fu, MD, PhD, Principal Investigator, Hill Top Research

More Information

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Record first received: February 10, 2006
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Health Authority: United States: Food and Drug Administration
ClinicalTrials.gov processed this record on 2006-02-15