

Effectiveness of coconut oil in the control of pediculosis capitis in preschoolers in Acapulco, Guerrero, Mexico

Submission date 04/11/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/11/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/05/2017	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Pediculosis capitis, more commonly referred to as head lice, is a common problem among children in Acapulco, Mexico. Although not a life-threatening condition, a head lice infection can cause great distress through discomfort and the negative associations people have with head lice. Insecticides (chemicals which kill insects) are the most common treatment for head lice. The overuse of these chemicals has led to the development of lice which are resistant, and can survive even after the application of chemicals. In recent years, there have been many attempts to develop alternative treatments at a low cost. Acapulco has a nearby coastal strip where coconut palms are grown and from which oil can be extracted for different uses, such as for skin moisturisation and sunscreen. The aim of this study is to investigate the effectiveness of coconut oil as a treatment for head lice in children attending kindergartens in Acapulco.

Who can participate?

Children attending a participating kindergarten aged between four and six years old.

What does the study involve?

Participating kindergartens are randomly allocated to one of two groups. In kindergartens in the first group, children have 30ml coconut oil applied onto their scalp, which is repeated 10 days later. In kindergartens in the second group, children continue as normal and have no additional treatment applied. At the start of the study and then seven days after those in the first group have had their final application of coconut oil, in both groups, children's scalps are inspected for head lice.

What are the possible benefits and risks of participating?

Participants who receive the treatment benefit from receiving treatment free of charge that they would otherwise not have received. There are no risks associated with participating.

Where is the study run from?

Eight schools in Acapulco (Mexico)

When is the study starting and how long is it expected to run for?
July 2012 to August 2016

Who is funding the study?
Universidad Autónoma de Guerrero (Mexico)

Who is the main contact?
1. Dr Sergio Paredes-Solís (scientific)
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2. Mrs Janet Saldaña-Almazán (public)
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Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ECOPC-CIET-PT

Study information

Scientific Title

Effectiveness of coconut oil in the control of pediculosis capitis in preschoolers in Acapulco, Guerrero, Mexico: A pilot randomized controlled cluster trial

Acronym

ECOPC-CIET-PT

Study objectives

Coconut oil is effective as a topical treatment for pediculosis capitis in preschoolers.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee Research Center for Tropical Diseases at the Autonomous University of Guerrero, ref: 2015-005

Study design

Cluster randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Pediculosis capitis

Interventions

Eight kindergarten's from zone 20 of the Ministry of Education of Guerrero, Acapulco city, are randomised to one of two groups using a computerised random number generator (www.random.org). At baseline, an initial measurement will be undertaken to estimate the prevalence of pediculosis capitis in each of the kindergartens. This involves a short questionnaire answered by the children's parents, the provision information about the study and provision of informed consent.

Intervention group: Following collection of the baseline measurement, students have 30 ml of coconut oil applied onto their scalp, which is repeated 10 days later.

Control group: Participants do not receive any treatment and continue as normal.

Follow up for all participants involves measuring the rate of pediculosis capitis infestation throughout direct inspection of the scalp at each kindergarten one week later of the last visit to the intervention schools (day 17)

Intervention Type

Other

Primary outcome measure

Pediculosis capitis infestation rate in school children is measured by direct observation in eight areas of 2x2cm on the scalp of each student, at baseline and 17 days.

Secondary outcome measures

Pediculosis capitis infestation level in school children is measured by direct observation in eight areas of 2x2cm on the scalp of each student, at baseline and 17 days.

Overall study start date

22/08/2014

Completion date

27/05/2016

Eligibility

Key inclusion criteria

1. Children attending school the day of the survey
2. Age between four and six years

Participant type(s)

Other

Age group

Child

Lower age limit

4 Years

Upper age limit

6 Years

Sex

Both

Target number of participants

Total participants 600, 8 clusters with approximately 75 children per cluster

Key exclusion criteria

Preschoolers with serious illnesses such as cancer, immune disease or disability.

Date of first enrolment

25/01/2015

Date of final enrolment

15/03/2015

Locations

Countries of recruitment

Mexico

Study participating centre

Jose Antonio Adame School

Paseo de la Cañada s/n

Colonia Alta Progreso

Acapulco

Mexico

39610

Study participating centre

Educadora Guerrerense School

Paseo de la comunidad s/n

Colonia Módulo Social Foviste

Acapulco

Mexico

39500

Study participating centre

Teresa Gaminde School

Campeche s/n
Colonia Progreso
Acapulco
Mexico
39350

Study participating centre**2 de Febrero School**

Calle Libertad de Expresión s/n
Colonia Los Periodistas
Acapulco
Mexico
39613

Study participating centre**Aaron M. Flores School**

Calle Paseo de la Cañada s/n
Colonia Alta Progreso
Acapulco
Mexico
39610

Study participating centre**Rubén Darío School**

Calle 2 s/n
Colonia Ampliación Palma Sola
Acapulco
Mexico
39510

Study participating centre**Vicente Guerrero School**

Avenida División del Norte s/n
Colonia Francisco Villa
Acapulco
Mexico
39610

Study participating centre

Independencia de México School
Avenida 16 de Septiembre s/n
Colonia 13 de Junio
Acapulco
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39350

Sponsor information

Organisation

Universidad Autónoma de Guerrero

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Sponsor type

University/education

Website

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ROR

<https://ror.org/054tbkd46>

Funder(s)

Funder type

University/education

Funder Name

Universidad Autónoma de Guerrero

Results and Publications

Publication and dissemination plan

Planned publication of study results in a peer reviewed journal.

Intention to publish date

21/07/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Lic. Janet Saldaña-Almazán (janetsaldana22@hotmail.com) or Dr. Sergio Paredes-Solís (srgprds@gmail.com)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		10/05/2017	25/05/2017	No	No