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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

Registration date
08/11/2016

Overall study status
Completed

Last Edited
25/05/2017

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Cluster randomized controlled trial

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 Years

Upper age limit
6 Years

Sex
All

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 Fovisste
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
Mexico
39350

Sponsor information

Organisation
Universidad Autónoma de Guerrero

ROR
https://ror.org/054tbkd46

Funder(s)

Funder type
University/education

Funder Name
Universidad Autónoma de Guerrero

Results and Publications

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