ISRCTN44215995 https://doi.org/10.1186/ISRCTN44215995

Effect of repeated four-monthly albendazole treatments on malaria in pre-school children living in communities endemic for Ascaris lumbricoides: a double-blind placebo-controlled randomised trial

Submission date	Recruitment status
28/07/2008	No longer recruiting
Registration date	**Overall study status**
25/09/2008	Completed
Last Edited	**Condition category**
16/04/2010	Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Deworming does not increase the incidence of malaria or the frequency of malaria attacks in pre-school children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics and Research Committee of Obafemi Awolowo University Teaching Hospitals' Complex (Nigeria) gave approval on the 13th April 2006 (ref: ERC/2006/03/16)

Study design
Double-blind placebo-controlled randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Malaria, helminth parasitisation

Interventions
There were two groups: the treatment (albendazole) group and the placebo group. A dose of 200 mg (one tablet) of albendazole was given to children aged 1 year. A dose of 400 mg (two tablets) of albendazole was given to children aged 2, 3 and 4 years. Children who were in the placebo group and aged 1 year were given one placebo tablet and children aged 2, 3 and 4 years were given two placebo tablets.

Children were given treatment or placebo at baseline, 4, 8 and 12 months and then followed up for the last time at 14 months. Children in the placebo group were treated with albendazole at 14 months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Albendazole

Primary outcome measure
1. Incidence of malaria, measured at baseline and 4, 8, 12 and 14 months
2. Malaria attacks, measured at baseline and 4, 8, 12 and 14 months
3. Infection with soil-transmitted helminths, measured at baseline and 4, 8, 12 and 14 months

Secondary outcome measures
1. Nutritional status, measured at baseline and 14 months
2. Haemoglobin, measured at baseline and 4, 8, 12 and 14 months

Overall study start date
16/05/2006

Completion date
22/08/2007

Eligibility

Key inclusion criteria
Pre-school children aged 12 - 59 months, either sex

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Months

Upper age limit
59 Months

Sex
Both

Target number of participants
1055

Key exclusion criteria
1. Severe anaemia less than 5 g/dl
2. Severe malaria

Date of first enrolment
16/05/2006

Date of final enrolment
22/08/2007

Locations

Countries of recruitment
Ireland

Nigeria

Study participating centre
Department of Zoology
Dublin
Ireland
02

Sponsor information

Organisation
The University of Dublin (Ireland)

Sponsor details
Trinity College
Dublin
Ireland
02

Sponsor type
University/education

Website
http://www.tcd.ie/

ROR
https://ror.org/05m7pjf47

Funder(s)

Funder type
Government

Funder Name
Health Research Board (HRB) (Ireland)

Alternative Name(s)
HRB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	anthelmintic results	19/02/2009		Yes	No