

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

28/07/2008

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

25/09/2008

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

16/04/2010

Condition category

Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

Department of Zoology
The University of Dublin
Trinity College
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Ireland
02

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 |