

# Double-blind, placebo-controlled study of nitazoxanide suspension in the treatment of cryptosporidiosis in children with HIV

**Submission date**  
10/06/2008

**Recruitment status**  
No longer recruiting

Prospectively registered

Protocol

**Registration date**  
16/06/2008

**Overall study status**  
Completed

Statistical analysis plan

Results

**Last Edited**  
15/03/2010

**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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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

High dose prolonged treatment with nitazoxanide for the treatment of cryptosporidiosis in children with HIV: a double-blind, randomised placebo-controlled trial

### Study objectives

The primary objective of the study is to evaluate the efficacy and safety of nitazoxanide oral suspension compared to a placebo in the treatment of cryptosporidiosis in children with HIV.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Research Ethics Committee of the University of Zambia, School of Medicine. Date of approval: 27/06/2002 (ref: 004-06-02)

### Study design

Double-blind, randomised, placebo-controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

HIV-related opportunistic infection/ cryptosporidiosis

### Interventions

Nitazoxanide suspension: 200 mg twice a day (bid) for 28 days (if 1-3 years old) or 400 mg bid for 28 days (if 4-11 years old), or matching placebo.

Total duration of follow-up: 4 weeks. However, a provision was included to allow compassionate open-label treatment for children who did not respond. This could have allowed extension of the period of follow-up by 60 days, therefore, it was possible for the children to be followed up for 88 days in total.

### Intervention Type

Drug

**Phase**

Not Specified

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

nitazoxanide

**Primary outcome measure**

Proportion of children achieving 'well' clinical response and time to 'well' clinical response. Well response is defined as the patient experiencing no symptoms of *C. parvum* infection and passing no watery stools within the previous 48 hours.

**Secondary outcome measures**

1. Proportion of children achieving eradication of oocysts of *C. parvum* from two consecutive stool samples, and time to eradication
2. Time to well clinical response and eradication of oocysts from the stool
3. Mortality at 4 weeks
4. Rate of reduction in diarrhoea frequency based on daily evaluation over 4 weeks
5. Nutritional response (change over time in weight for age z scores, weight for height z scores, height for age z scores and mid-upper arm circumference) based on daily evaluation over 4 weeks

**Overall study start date**

01/06/2002

**Completion date**

01/06/2004

**Eligibility****Key inclusion criteria**

1. Both males and females, age 1-11 years
2. Stool positive for *Cryptosporidium parvum* using the auramine phenol staining technique (specimen collected within 7 days prior to enrolment)
3. Patients with diarrhoea ( $\geq 3$  unformed stools/day) for each of the 5 days prior to enrolment based on report by the patient, parent or guardian and observation in hospital for at least 24 hours
4. Patients who are HIV positive by the Capillus Rapid Test (Trinity Biotech, Ireland)

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

1 Years

**Upper age limit**

11 Years

**Sex**

Both

**Target number of participants**

60

**Key exclusion criteria**

1. Any investigational drug therapy within 1 month of enrolment
2. Use within 2 weeks of enrolment of metronidazole, tinidazole, ornidazole, secnidazole, hydroxyquinoline derivatives, diloxanide, paromomycin or nitazoxanide
3. Patients with positive enzyme immunoassay of faecal sample for *Entamoeba histolytica* or *Giardia lamblia*
4. Serious systemic disorders incompatible with the study

**Date of first enrolment**

01/06/2002

**Date of final enrolment**

01/06/2004

**Locations****Countries of recruitment**

Zambia

**Study participating centre****Tropical Gastroenterology & Nutrition group**

Lusaka

Zambia

50398

**Sponsor information****Organisation**

Romark Laboratories (USA)

**Sponsor details**

6200 Courtney Campbell Causeway

Suite 880

Tampa

United States of America

33607

**Sponsor type**

Industry

**Website**

<http://www.romark.com>

**ROR**

<https://ror.org/00982nx75>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Romark Laboratories (USA)

## 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?
<a href="#">Results article</a>	results	02/12/2009		Yes	No