

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

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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 (≥ 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 02/12/2009 | | Yes | No |