ISRCTN41089957 https://doi.org/10.1186/ISRCTN41089957

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

Submission date	Recruitment status	[_] Prospectively registered
10/06/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/06/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/03/2010	Infections and Infestations	

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

RM02-3013

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