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A randomised double blind controlled trial of nitazoxanide in intestinal polyparasitism in humans: a Brazilian study

Submission date	Recruitment status	[_] Prospectively registered
27/06/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/09/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/09/2008	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
A randomised double blind controlled trial of nitazoxanide of the treatment in intestinal polyparasitism in humans

Study objectives

Nitazoxanide is a drug with an ample spectrum of activity, a superior or equivalent effectiveness to secnidazole and/or albendazole in the treatment of majority of intestinal parasitism in humans, and presents with less adverse effects than the previously cited drugs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Committee of Ethics in Research in Human Beings of Propesq/UFJF, dated 15th March 2007 (ref: 063/2007)

Primary study design
Interventional

Study design
Randomised double blind controlled trial, single centre

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Intestinal polyparasitism

Interventions
1. Nitazoxanide = 15 mg/kg/day every 12 hours for children, 500 mg tablet every 12 hours for adults, during three days
2. Secnidazole = 30 mg/kg/day for children and 2 g for adults in one dose
3. Albendazole = 400 mg in one dose (suspension for 400 mg for children, tablets of 400 mg for adults)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Nitazoxanide, secnidazole, albendazole

Primary outcome(s)
1. Cure (non-infected) defined as an absence of any species of parasite in the examination of excrements
2. Cure absence (infected) defined as maintenance of the pre-existing parasite

These outcomes will be measured in July and September 2008.

Key secondary outcome(s)
Prevalence of adverse effects. These outcomes will be measured in July and September 2008.

Completion date

30/09/2008

Eligibility

Key inclusion criteria
1. Participants more than one year of age, either sex
2. Positive for one or more species of intestinal parasites
3. Rural populations in the Zona da Mata of the State of Minas Gerais (Brazil)
4. Taken care of by the Unified National Health System (SUS)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Intestinal obstruction for intestinal parasitisms
2. Pregnant
3. Patients with liver or renal insufficiency
4. Alterations in biliary treatment
5. Patient is using warfarin, aspirin, phenytoin, carbamazepine or valproic acid

Date of first enrolment
01/07/2008

Date of final enrolment
30/09/2008

Locations

Countries of recruitment
Brazil

Study participating centre
Rua Padre Vieira, 50/302
Minas Gerais
Brazil
36025070

Sponsor information

Organisation
Federal University of Juiz de Fora (Brazil)

ROR
https://ror.org/04yqw9c44

Funder(s)

Funder type
University/education

Funder Name
Federal University of Juiz de Fora (Brazil)

Funder Name
Farmoquimica S/A (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration