

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

Submission date 27/06/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/09/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/09/2008	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mrs Elisabeth Andrade

Contact details

Rua Padre Vieira, 50/302

Minas Gerais

Brazil

36025070

+55 32 3232 2816

ecampos@terra.com.br

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 Propeq/UFJF, dated 15th March 2007 (ref: 063/2007)

Study design

Randomised double blind controlled trial, single centre

Primary study design

Interventional

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