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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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)

Study design
Randomised double blind controlled trial, single centre

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
Prevalence of adverse effects. These outcomes will be measured in July and September 2008.

Overall study start date
01/07/2008

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

Age group
Other

Sex
Both

Target number of participants
60

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
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36025070

Sponsor information

Organisation
Federal University of Juiz de Fora (Brazil)

Sponsor details
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Sponsor type
University/education

Website
http://lattes.cnpq.br/0143686778100049

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

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