Effect of Dientamoeba fragilis eradication on symptoms in children with abdominal pain

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Effectiveness of treatment with clioquinol on parasitologic eradication is being studied as well as the clinical effectiveness of eradication in children with dientamoeba fragilis infection.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal signs and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON30565

Source
ToetsingOnline

Brief title
Symptoms, Dientamoeba Fragilis and Clioquinol

Condition

- Gastrointestinal signs and symptoms
- Protozoal infectious disorders

Synonym
dientamoeba fragilis infection, parasitic bowel infection

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: onderzoeksgeld uit voorafgaande studies

Intervention

Keyword: clioquinol, Dientamoeba fragilis, pediatric, symptoms

Outcome measures

Primary outcome

Change in symptoms in children with dientamoeba fragilis after treatment with

clioquinol and placebo.

Parasitological eradication

Secondary outcome

In de gebruikte duur en dosering van behandeling worden zelden bijwerkingen

gezien. In zeer hoge dosering kan het middel neurotoxisch zijn.

Study description

Background summary

Dientamoeba fragilis infection is associated with gastrointestinal symptoms in a lot of children. Few studies evaluating tratment of D. fragilis infection in children are available. Drugs that have been used are: iodoquinol, paromomycine (Humatin), metronidazol en tetracycline. In the USA the first choice for therapy is iodoquinol and second choice is paromomycin. Because iodoquinol is not available in the Netherlands, clioquinol is currently used for treatment of D. fragilis. In children treated in the Academic medical Centrum (AMC) in Amsterdam, clioquinol proved to be effective for eradication of the parasite and dissapearance of symptoms. Studies towards effectiveness of clioquinol in children with D. fragilis have, as far as we know, not been described.

Study objective

Effectiveness of treatment with clioquinol on parasitologic eradication is being studied as well as the clinical effectiveness of eradication in children with dientamoeba fragilis infection.

Study design

The effectiveness of clioquinol will be evaluated in a cross-over treatment.

One part of the population will be treated with paromomycin 15 mg/kg/day during 7 days, the other part with placebomedication. After 14 days the group that received clioquinol will now receive placebo and vice versa. A diary is being held starting 4 days before treatment untill 3 weeks after start of treatment. With this diary changing of symptoms can be studied optimally. 3 weeks after te start of treatment a TFT-test is being done followed by parasitologic evaluation. The primary endpoint is clinical effectiveness, the secondary endpoint parasitological effectiveness.

Study burden and risks

As found in literature clioquinol in normal doses has limited side-effects. Only in very high doses neurotoxicity has been reported.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

infection with dientamoeba fragilis
age between 4 and 18 years old

Exclusion criteria

co-infection with a pathogen
IBD (colitis Ulcerosa)
Oncologic patients
immune compromised patients

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2006
Enrollment:	70
Type:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL14810.067.06