Dientamoeba fragilis: clinical symptoms, optimal treatment and molecular detection

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1. To determine clinical symptoms of Dientamoeba fragilis infection. 2. To evaluate the efficacy and safety of clioquinol versus metronidazol in the treatment of Dientamoeba fragilis in children.3. To evaluate the duration of positive PCR...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Protozoal infectious disorders
Study type	Interventional

Summary

ID

NL-OMON39247

Source
ToetsingOnline

Brief title
Dientamoeba fragilis

Condition

- Protozoal infectious disorders

Synonym
'Dientamoeba fragilis infection'; 'parasitic gut-infection'

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: wetenschapsfonds van het betreffende ziekenhuis

Intervention

Keyword: Clioquinol, Dientamoeba fragilis, Metronidazole, PCR

Outcome measures

Primary outcome

To determine differences in efficacy of anti-protozoal treatment with

clioquinol or metronidazole in children with symptomatic Dientamoeba fragilis

infection.

Secondary outcome

- To determine symptoms of Dientamoeba fragilis infection in children and adults

- To assess duration of positivity of PCR after treatment

- To determine incidence in non-symptomatic patients

Study description

Background summary

Dientamoeba fragilis is a world-wide, anaerobic intestinal parasite, first described in 1918 by Jepps and Dobell. Since the first description there has been doubt about the pathogenicity of an infection. In recent years there has been an increase in evidence on its pathogenicity. (1)
Numerous studies around the globe have described a distinct difference in Dientamoeba fragilis infections, there is a large number of asymptomatic patients and on the other hand there is a group of patients with symptoms that decrease after treatment.1,2 Especially children tend to have more symptomatic infections, and benefit by treatment. (3,4)

Symptoms described are mainly abdominal pain, diarrhea, flatulence, fatigue and anorexia. It is not known if an infection could be self-limiting. (1-3)

Prevalence rates of D. fragilis differ throughout the world.1 Up until now, a cyst-stage of Dientamoeba fragilis has never been found, which made detection of an infection difficult.
New techniques, such as better fixatives and the development of the triple faeces test in the Netherlands have improven diagnostics. (4)

In Friesland, PCR techniques are used to detect an infection. In the presence of D. fragilis DNA, PCR becomes positive. The introduction of PCR in 2008 in Friesland has caused a far higher prevalence of D. fragilis than expected.

Up until now there is a limited amount of information available on the efficacy of anti-protozoal treatment. No large-scale trials have been performed. Current medical practice in children is to treat a symptomatic infection. In a retrospective study by Bosman et al, conducted in 2004 among 43 children with D. fragilis infections, treatment with clioquinol, metronidazol or tinidazol was effective in reducing the symptoms in 81% of children with eradication after therapy. In 33 of 43 children (77%) mono-therapy was sufficient to eradicate D. fragilis.(4)
As stated above, Dientamoeba fragilis is the cause of gastro-intestinal symptoms, especially in children. Treatment with anti-protozoal drugs is started in symptomatic patients, while there is no data available on best possible treatment. This study can give more information about the efficacy and safety of the most frequent used anti-protozoa in children in the Netherlands. Moreover, it can provide some information about the natural cause of an infection and PCR techniques in the detection of Dientamoeba fragilis infections.

REFERENCES
1. Johnson EH, Windsor JJ, Clark CG. Emerging from obscurity: biological, clinical and diagnostic aspects of dientamoeba fragilis.
Clin Microbial Reviews 2004;17(3):553-70
2. Johnson J, Clark CG. Cryptic genetic diversity in Dientamoeba fragilis. J Clin Microbiol 2000; 38:4653
3. Stumpel OFB, Tolboom JJM, Warris A. Dientamoeba fragilis, vooral bij kinderen pathogeen? Tijdschr infectieziekten 2006;1(4):155-59
4. Bosman DK, Benninga MA, Gool T van. Dientamoeba fragilis: een mogelijk belangrijke oorzaak van persisterende buikpijn bij kinderen. Ned Tijdschr Geneeskd. 2004;148:875-9

Study objective

1. To determine clinical symptoms of Dientamoeba fragilis infection.
2. To evaluate the efficacy and safety of clioquinol versus metronidazol in the treatment of Dientamoeba fragilis in children.
3. To evaluate the duration of positive PCR testresults after treatment

Study design

A prospective, double-blind, randomised trial

Intervention

After informed consent from parents and/or patient, participants will be treated with Clioquinol 15 mg/kg/day in 3dd for 10 days or metronidazol 30 mg/kg/day in 3dd for 10 days.

Study burden and risks

Subjects and/or their legal guardians will be asked to complete a questionnaire about clinical symptoms. At inclusion, patients have already provided a stool sample for PCR.
Subjects will collect the stool samples at home.
Treatment for subjects will be the same as for non-included patients, as current medical practice in symptomatic children is treatment with clioquinol or metronidazol.
The extra burden for subjects will be filling in the questionnaire at inclusion and follow-up, and the handing in of extra stool samples.
There will be no direct benefit for included patients. The benefit for future patients with Dientamoeba fragilis will be the most optimal treatment.

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

- Subjects in between 0 and 18 years of age
- Positive PCR for Dientamoeba fragilis

Exclusion criteria

- Contra-indication for the use of Metronidazole or Clioquinol
- Pregnancy
- Underlying disease or use of medication

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2010
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	21-06-2010
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	06-09-2010
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	07-05-2013
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	11-06-2013
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL31490.099.10