The growth retardation and outcomes with therapy (growth) study: A prospective evaluation in pediatric Crohn*s disease

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Identifying subsets of Crohn's disease (CD) at risk for poor outcomes is a priority in pediatric CD research. Having the ability to predict patients more likely to relapse, to be refractory to therapy or to develop complications may enable...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON37234

Source
ToetsingOnline

Brief title
Growth

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease, Inflammatory Bowel Disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: calpro,glycominds,voornamelijk eigen budget;transport bepalingen en kosten bepalingen worden gefinancierd door degenen die deze testen op de markt hebben;zijnde glycominds en calpro (zie ook G2)

Intervention

Keyword: Crohn's disease, growth retardation, outcome, Pediatric

Outcome measures

Primary outcome

Primary study parameters are clinical and therapeutic parameters that predict

disease relapse and other outcomes of pediatric Crohn's disease such as linear

growth, penetrating or stricturing disease and requirement for surgery.

Secondary outcome

NA

Study description

Background summary

Crohn's disease (CD) is a chronic inflammatory disorder of the gastrointestinal tract that can affect both children and adults, of unknown etiology. The course of the disease is characterized by periods of remission and relapse, or continuous clinical symptoms. Disease activity is characterized (upon histopathology) by transmural inflammation of the gut, most typically in the ileum or colon, though it may involve any section of the gut. Clinically, this inflammation may lead to abdominal pain, diarrhea, rectal bleeding, weight loss and decreased growth velocity, as well as a myriad of other symptoms. Complications may include growth failure, perianal disease, strictures, internal fistulae or abscesses, and may require surgery in close to 50% of patients over time.

Study objective

Identifying subsets of Crohn's disease (CD) at risk for poor outcomes is a priority in pediatric CD research. Having the ability to predict patients more likely to relapse, to be refractory to therapy or to develop complications may enable physicians to treat these subsets more aggressively at disease onset, or

early in the course of the disease, without exposing all pediatric patients to medications that increase the risk for neoplasia, and not to wait for complications before instituting more aggressive maintenance therapy. There are no prospective studies that have evaluated this issue in new onset, treatment naïve pediatric CD.

Study design

The "Growth study" is an observational, prospective, inetrnational multicenter study.

Study burden and risks

Patients included in this study will not have any risks since no interventions take place. The burden is minimal since the standardized visits are combined with the regular visits. Drawing of blood also will be combined with the regular blood drawings.

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

Newly diagnosed Crohn's disease, untill age of 18

Exclusion criteria

Abdominal surgery, pregnancy and indeterminate colitis.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2008
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	25-09-2008

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-03-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-06-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL23131.078.08