Comparison between venous infliximab blood level and bloodspot-technology in children with inflammatory bowel disease.

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The primary objective of this pilot study is to compare the venous infliximab blood level and anti-drug-antibodies with the bloodspot-technology in children with inflammatory bowel disease. The hypothesis is that there will be a good correlation...

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

Summary

ID

NL-OMON45579

Source
ToetsingOnline

Brief title
Comparison between venous infliximab blood level and bloodspot-technology.

Condition

- Gastrointestinal inflammatory conditions

Synonym
chronic inflammation of the bowel, Inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Sanquin afdeling Diagnostiek,Sanquin Bloedbank

Intervention

Keyword: Bloodspot technology, Inflammatory Bowel Disease, Infliximablevel, Pediatric

Outcome measures

Primary outcome

The primary study objective is comparison between the venous infliximab blood

level/anti-drug-antibodies and the bloodspot-technology.

Secondary outcome

Not apply

Study description

Background summary

Inflammatory bowel disease include Crohn*s disease, Ulcerative Colitis and IBD-unclassified which presents during childhood and adolescence in 25% of its patients. The incidence has risen the recent decades. Increased concentrations of tumor necrosis factor-* (TNF*) are found in the mucosa of IBD patients. This key role of TNF* has led to the development of biologic therapy based on the administration of monoclonal antibodies which bind and inactivate TNF*, for example infliximab. Efficacy of the treatment is correlated with the blood level and the development of anti-drug-antibodies. The infliximab blood levels are measured through venous collection of blood. Recently Sanquin developed a bloodspot-technology to measure the infliximab blood level and anti-drug-antibodies with a bloodspot collected in a small tube. This capillary blood sample is less intense for children and can be measured easier and more often.

Study objective

The primary objective of this pilot study is to compare the venous infliximab blood level and anti-drug-antibodies with the bloodspot-technology in children with inflammatory bowel disease.
The hypothesis is that there will be a good correlation between this blood levels, so that the bloodspot-technology can be used in the pediatric

population with inflammatory bowel disease.

Study design

We will perform a prospective clinical pilot study.

Study burden and risks

When our hypothesis is correct this will be beneficial for children with inflammatory bowel disease in the future. The treatment can be better adapted to the individual patient. In case of complaints the blood levels will be easier to determine on which the infliximab dosage can be adapted. The capillary blood collecting is the additional achievement that the patients undergo. Potential hazards of a capillary blood collection, for example hematoma or sensitivity of the finger, are minimal. The risk associated with the blood withdrawal can be considered negligible and the extra burden will be minimal.

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

- Patients with Crohn's disease, Ulcerative Colitis and IBD-unclassified
- Age from six to sixteen years old
- Treatment with infliximab
- Indication to determine infliximablevel and anti-drug-antibodies
- Obtain informed consent

Exclusion criteria

- Age under six and above seventeen years old
- No informed consent
- Children and parents/guardians who do not speak the Dutch language

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-10-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	02-06-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-03-2018
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	NL60785.078.17