# Paediatric Inflammatory Bowel Diseases Network for Safety, Efficacy, Treatment and Quality improvement of care: The PIBDNet inception cohort and safety registry

Published: 29-11-2016
Last updated: 24-05-2024

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

## Summary

### ID

NL-OMON53060

**Source**
ToetsingOnline

**Brief title**
PIBD-SETQuality

### Condition

- Gastrointestinal inflammatory conditions

**Synonym**
chronic inflammation of the bowel, Inflammatory bowel disease

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Université Descartes
**Source(s) of monetary or material Support:** Horizon 2020 tot 2024;hierna PIBDNet.

## Intervention

**Keyword:** Inception cohort, Inflammatory bowel disease, Pediatric, Safety registry

## Outcome measures

### Primary outcome

The outcome of the study is the identification of factors predictive for

outcome, specific severe adverse events (SAEs) and for predictors of response

or non-response to therapy and the identification of rare complications of

disease or treatment in PIBD.

### Secondary outcome

Not applicable

# Study description

### Background summary

The incidence of paediatric onset Inflammatory Bowel Diseases (PIBD) has risen dramatically in recent decades. Compared to adult forms, PIBD reflects a more severe disease. Paediatric patients more often requiring aggressive treatment with immunomodulators. Thereby children are exposed to a life-long risk of both serious disease and treatment-related adverse events, such as infections and malignancies. In addition, the risk profile for severe adverse events might differ between children/adolescents and adults with IBD. Therefore, there is an urgent need to generate a prospective large long term real world inception cohort designed to analyze effectiveness and safety signals and correlate them to individual risk factors in well phenotyped patients. Many side effects and complications are rare and so to identify and study these in addition to the inception cohort there is a requirement to establish a process for identifying these complications using a European wide paediatric IBD safety monitoring registry, next to the inception cohort.

### Study objective

The primary objective of the PIBD-NET inception cohort is to search for factors predictive for outcome, specific severe adverse events (SAEs) and for predictors of response or non-response to therapy.
The secondary objective is the identification of rare complications of disease or treatment in PIBD.

### Study design

An observational registry including a subcohort of patients with biobanking will be set up and collection of safety signalling on a wide scale will be performed.
A robust and highly secured prospective multicentre long term database tool (PIBD-cloud) for PIBD will be created in collaboration with a highly experienced IT small/medium-size enterprise (SME) (WP6). Newly diagnosed patients will be identified and carefully phenotyped. Patients will be closely monitored for disease progression during follow up.
Next to this, a pan-European safety registry of rare complications of drugs and the disease will be created.

### Study burden and risks

Both the inception cohort study and the safety registry do not bring any risks for the patients. The burden is considered 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)
Babies and toddlers (28 days-23 months)

## Inclusion criteria

Children with newly diagnosed IBD (age 0-18 years)

## Exclusion criteria

- Insufficient knowledge of national language
- Informed consent of patient or parents has not been obtained
- Severe co-morbidity

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |

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|---|---|
| Start date (anticipated): | 03-01-2017 |
| Enrollment: | 500 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Registration: | No |

## Ethics review

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|---|---|
| Approved WMO Date: | 29-11-2016 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 28-05-2018 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 28-10-2019 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 01-02-2022 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 18-04-2024 |
| 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 | NL57248.078.16 |