

# Is it useful to monitor thiopurine metabolites in pediatric patients with Crohn's disease on combination therapy? A multicenter prospective observational study

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Study

Ongoing

## Administrative details

### EU PAS number

EUPAS38918

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### Study ID

40080

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### DARWIN EU® study

No

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### Study countries

Czechia

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### Study status

Ongoing

## Research institutions and networks

## Institutions

Motol University Hospital (FNM)

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Institution

2nd Faculty of medicine, Charles University

Department of Pediatrics, Faculty of Medicine and  
Dentistry, Palacky University and University  
Hospital Olomouc, Czech Republic

## Contact details

### Study institution contact

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Study contact

[potuznikovakris@gmail.com](mailto:potuznikovakris@gmail.com)

### Primary lead investigator

Kristyna Pospisilova

## Study timelines

### **Date when funding contract was signed**

Actual: 01/01/2012

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### **Study start date**

Actual: 15/01/2016

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### **Date of final study report**

Planned: 13/01/2021

## Sources of funding

- Other

## More details on funding

Ministry of Health, CZ 00064203, University Hospital Motol, Prague, CZ, and 0098892, University Hospital, Olomouc, CZ, Ministry of Education, Youth and Sports, CZ OP VVV ENOCH CZ.02.1.01/0.0/0.0/16\_019/0000868

## Study protocol

[PROTOKOL\\_AZA.pdf](#) (277.85 KB)

## Regulatory

## Was the study required by a regulatory body?

No

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## Is the study required by a Risk Management Plan (RMP)?

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

#### **Main study objective:**

We prospectively observed a group of pediatric patients with Crohn's disease on combination therapy (infliximab and azathioprine) in order to find suitable 6-thioguanine (as active metabolite of thiopurine therapy) cutoff levels in erythrocytes. In children, the target 6-thioguanine levels in combination therapy are not yet known.

## Study Design

## **Non-interventional study design**

Cohort

Other

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## **Non-interventional study design, other**

Pharmacokinetic study

## Study drug and medical condition

### **Study drug International non-proprietary name (INN) or common name**

AZATHIOPRINE

INFLIXIMAB

## Population studied

### **Age groups**

- Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - Adults (18 to < 46 years)
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### **Estimated number of subjects**

63

## Study design details

### **Outcomes**

Evaluation of the relationship between 6-thioguanine levels and infliximab through levels, - Investigation of thiopurine metabolites as potential predictors of relapse - Revealing non-adherence to thiopurine therapy and 'shunters' - Evaluation of possible relationship between infliximab and thiopurine metabolites levels and markers of disease activity

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### **Data analysis plan**

For data analysis R statistical software is used. Since we collected data from repeated measurements (from each patient), linear mixed model analysis was performed. When searching for optimal cutoffs cross-validated ROC analysis were used. To assess the risk of loss of response to infliximab survival analysis was performed.

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

### **Conflicts of interest of investigators**

[AZA\\_IFX\\_COI.pdf](#) (84 KB)

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## Data sources

### **Data sources (types)**

Other

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**Data sources (types), other**

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No