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

Study ID

40080

DARWIN EU® study

No

Study countries

☐ Czechia

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

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Study contact

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Primary lead investigator

Kristyna Pospisilova

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 01/01/2012

Study start date
Actual: 15/01/2016

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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

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)

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

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)

Data sources

Data sources (types)

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No