Impact of diagnostic delay on drug utilization and use of healthcare facilities in patients with ulcerative colitis: observational study on real-world data taKen from the AdmInistRative healthcare database Of TuScany RegIon, Italy (The KAIROS-II study)

First published: 14/10/2021

Last updated: 23/04/2024

Study Planned

Administrative details

EU PAS number

EUPAS43705

Study ID

43706

DARWIN EU® study

No

Study countries

Italy

Study description

This project will firstly evaluate diagnostic delay (DD) in patients with ulcerative colitis (UC). Then, we will explore the impact of DD on effectiveness and safety clinical outcomes. We will perform a retrospective cohort study. Data will be retrieved from the administrative healthcare databases of Tuscany, an Italian region. Patients will be included if they have a first record of ICD-9 diagnosis or co-payment exemption code of UC from June 1st, 2011 to December 31st, 2018 (index date, ID). Patients <18 years old at ID or with look-back period <5 years or follow-up period <2 years will be excluded. DD was defined by a record of emergency department (ED) access or hospitalization for gastrointestinal causes in the 7-60 months (7-18 months: short DD, 19-60 months: long DD) preceding ID. Patients with an ED access or hospitalization for gastrointestinal causes recorded in the 6 months before the ID or with none of these records were considered timely diagnosed (TD). We performed survival analyses (Kaplan-Meier curves) for effectiveness outcomes (time free from the first: dispensation of azathioprine, advanced therapy and surgery) and safety outcomes (time free from the first: ED access and/or hospitalization for any cause) over a 2-years follow-up period. Adjusted hazard ratio (aHR) was calculated by using Cox models adjusted for age, gender and number of concomitant drugs. Both outcomes were evaluated for dichotomous (TD and DD) and categorical variables of DD (TD, short DD and long DD).

Study status

Planned

Research institutions and networks

Institutions

Unit of adverse drug reactions monitoring (UADRM), University Hospital of Pisa

Italy

First published: 08/01/2014

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Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility** | **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Marco Tuccori

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/03/2019

Actual: 29/03/2019

Study start date
Planned: 01/10/2021

Date of final study report
Planned: 01/10/2022

Sources of funding

- Other

More details on funding

Pisa University Hospital

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

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Healthcare facilities utilization

Main study objective:

This project will firstly evaluate diagnostic delay in patients with ulcerative colitis. Then, we will assess the impact of diagnostic delay on effectiveness and safety clinical outcomes by analyzing drug-utilization and healtchare facilities usage.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

AZATHIOPRINE

INFLIXIMAB

ADALIMUMAB

GOLIMUMAB

VEDOLIZUMAB

TOFACITINIB

USTEKINUMAB

Medical condition to be studied

Colitis ulcerative

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

3.500

Study design details

Outcomes

Diagnostic delay (DD): potential DD in patients with ulcerative - Drug utilization and effectiveness outcomes: time free from azathioprine, treatment with advanced therapy and surgery - Safety: time free from Emergency department access or hospitalization for any cause. All the outcomes will be evaluated for

both dichotomous and categorical variable of DD.

Data analysis plan

Diagnostic delay: We will tabulate the distribution of dichotomous and categorical variables of interest in the study population. We will compute Chi-squared test at significance level $\alpha = 0.05$ to assess if there is difference between categories in dichotomous and categorical variables. Drug-utilization, effectiveness and safety: Kaplan-Meier survival analysis and Hazard Ratio with corresponding 95% Confidence Interval.

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.

Data sources

Data source(s)

ARS Toscana

Data source(s), other

ARS

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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