Diagnostic delay, drug utilization and clinical effectiveness and safety outcomes in patients with Crohn’s disease: checKing and AssessIng Real wOrld data from healthcare adminiStrative databases in Tuscany, Italy. The KAIROS study (the KAIROS study)

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/38706

EU PAS number

EUPAS38705

Study ID

38706

DARWIN EU® study

No

Study countries

☐ Italy

Study description

This project will firstly evaluate diagnostic delay in patients with Crohn's disease. Then, drug utilization, adherence of standard treatment (budesonide) and efficacy and safety clinical outcomes will be evaluating by exploring their relationship with diagnostic delay. 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 disease exemption or a first record of dispensation of oral budesonide as CD patient from 6/1/2011 to 6/30/2016 (index date, ID). Patients <18 years old at ID or with look-back period <5 years or follow-up period <3 years will be excluded. Patients will be classified with DD if they have at least one access to emergency department (ED) or hospitalization for gastro-intestinal (GI) causes earlier than 6 months before ID, during the look-back period. A sub-group of patients will be selected for the drug-utilization analysis. Trajectories of adherence to drug treatment were computed with a three-step procedure for drug-utilization analysis: 1) computation of 24 statistical measures, 2) factor analysis, 3) cluster analysis. Clusters of patients will be described with a focus on DD occurrence. Clinical effectiveness and safety outcomes will be investigated through survival analyses and Hazard Ratio and corresponding 95% Confidence Interval will be estimated.

Study status

Planned

Research institutions and networks

Institutions

University Hospital of Pisa

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Institution

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: 01/01/2021

Date of final study report
Planned: 31/12/2021

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:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

This project will evaluate diagnostic delay in patients with Crohn's disease. Then, drug utilization, adherence of standard treatment (budesonide) and efficacy and safety clinical outcomes will be evaluating by exploring their relationship with diagnostic delay.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

BUDESONIDE

Medical condition to be studied

Crohn's disease

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

3000

Study design details

Outcomes

- Diagnostic delay (DD): potential DD in patients with Crohn’s disease - Drug utilization: patterns of utilization of budesonide in patients with Crohn’s disease for variables of DD - Effectiveness: clinical effectiveness outcomes of patients with Crohn’s disease for variables of DD - Safety: clinical effectiveness outcomes of patients with Crohn’s disease for variables 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: trajectory model approach. Effectiveness and safety: Kaplan-Meier survival analysis and Hazard Ratio with corresponding 95% Confidence Interval.

Data management

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