Real-world Prescription Pattern, Discontinuation and Costs of Ibrutinib-Naïve Patients with Chronic Lymphocytic Leukemia: An Italian Healthcare Administrative Database Analysis

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000153

Study ID

1000000153

DARWIN EU® study

No

Study countries

Italy

Study description

An observational retrospective non-interventional cohort study aimed to describe the prescription pattern of new users of ibrutinib affected by chronic lymphocytic leukemia (CLL), focusing on discontinuation, severe adverse events (AEs) and change of treatment, and to assess the healthcare expenditure directly charged to the Italian National Health Service (SSN). Out of new users of ibrutinib from 01/01/2016 to 12/31/2017, only patients with at least a primary or secondary in-hospital diagnosis of CLL (ICD-9-CM code 204.1*) from 01/01/2013 to 12/31/2018 were further broken down according to the ibrutinib's line treatment (first line—FL; second or later line—SLL) and analysed. They were characterized by sex and age in the selection period. Mean annual consumption (defined daily doses [DDD]), treatment discontinuation, changes of therapy, interruptions and healthcare costs in charge of the SSN were assessed during two follow-up years.

Study status

Finalised

Research institutions and networks

Institutions

Fondazione ReS (Ricerca e Salute), CINECA partner

Italy

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Institution | Not-for-profit | ENCePP partner

Contact details

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Study timelines

Date when funding contract was signed

Actual: 08/06/2019

Study start date

Actual: 08/07/2019

Date of final study report

Actual: 30/09/2019

Sources of funding

- No external funding

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Healthcare resource utilisation

Data collection methods:

Secondary use of data

Study design:

Adults with at least 1 supply of ibrutinib (index date) from 01/01/2016 to 12/31/2017 (accrual period) were selected. Only new users with at least 1

hospital discharge form including primary or secondary diagnosis of CLL (ICD-9-CM code 204.1*) from 01/01/2013 to 12/31/2018 were selected and analysed

Main study objective:

This analysis aimed to describe patients with CLL and new users of ibrutinib, in terms of its prescription pattern, focusing on discontinuation, severe AEs, and treatment change reimbursed by the SSN.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

IMBRUVICA

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

IBRUTINIB

Anatomical Therapeutic Chemical (ATC) code

(L01EL01) ibrutinib

ibrutinib

(L01XE27) ibrutinib

ibrutinib

Medical condition to be studied

Chronic lymphocytic leukaemia

Population studied

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Study design details

Setting

Inpatient and outpatient

Summary results

Out of more than 5 million inhabitants of the ReS database, 69 new ibrutinib users and diagnosed with CLL in 2016 (incidence: 1.6 × 100,000) and 41 in 2017 (incidence: 0.9 × 100,000) were selected. Of these, 21 (19.1%) were FL ibrutinib users and 89 (80.9%) were SLL ones, mostly males and with mean ages (±SD) of 65 ± 14 and 70 ± 10, respectively. The mean annual consumption among FL users decreased from 222.2 DDD per patient treated to 216.0 DDD, while increased among SLL patients from 238.6 DDD to 260.1 DDD, in the first and second follow-up year, respectively. The discontinuation rate was about 40% in the first year, similarly among FL and SLL users. SLL patients discontinued more frequently (52.8% vs 20.0%) in the second year. Very few AEs were recorded. The 62.5% of FL and 55.6% of SLL users discontinuing ibrutinib in 1-year follow-up, while one SLL patient (5.3%) in the second year changed therapy. The 20.0% and 15.9% of all new users in first and second

year interrupted ibrutinib. The total integrated cost of FL patients was €55,732 reducing by about €15,000, while it was €58,716 for SLL ones decreasing by €6,000, respectively, in the first and in the second year. Pharmaceuticals were the key cost driver (ibrutinib accounted for more than 77%).

Documents

Study publications

Real-world Prescription Pattern, Discontinuation and Costs of Ibrutinib-Naïve P...

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)

Database of Fondazione ReS

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes