Utilization patterns, access to healthcare facilities and economic assessment of JAKi drugs used in rheumatoid arthritis patients in Tuscany: the LEONARDO study

First published: 13/06/2020

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/37637

EU PAS number

EUPAS35746

Study ID

37637

DARWIN EU® study

No

Study countries

Italy

Study description

In this study, we will identify new users of JAKi in Tuscany from their approval in the treatment of severe to moderate RA in 2018 to 2019, and describe their utilization of the Regional Healthcare System facilities after treatment initiation, including an economic assessment. Since JAKi are used as second line in patients with moderate to severe RA non-responders to biologic DMARDs, we will provide an estimation over time of the new users of bDMARDs with and without history of access to rheumatoid arthritis wards in Tuscany.

Study status

Finalised

Research institutions and networks

Institutions

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

Italy

First published: 08/01/2014

Last updated: 16/02/2024

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

Pisa Scuola Superiore Sant'Anna

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Corrado Blandizzi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/06/2020

Actual: 01/07/2020

Study start date

Planned: 30/06/2020

Actual: 01/07/2020

Data analysis start date

Planned: 06/07/2020

Actual: 10/07/2020

Date of final study report
Planned: 31/07/2020

Actual: 16/10/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Galapagos NV

Study protocol

Study protocol (ENCEPP REGISTRY).pdf(846.63 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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

to identify and describe new users of JAKi in Tuscany from 2018 (year of approval in the treatment of severe to moderate RA) to 2019, and describe their utilization of the Regional Healthcare System facilities after treatment initiation, including an economic assessment

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AA29) tofacitinib

tofacitinib

(L04AA37) baricitinib

baricitinib

Population studied

Short description of the study population

In order to answer the research questions (RQ), we created three different study cohorts, as described in detail below.

For the RQ-1 and RQ-2, patients were identified by the first dispensation of a JAKi from January 1st, 2018 to December 31st, 2019. Cohort entry was defined by the first dispensation of a JAKi. We excluded patients with less than 10 years of records in the look back period, history of cancer or use of anti-cancer drugs in the look back period, as well as those aged ≤ 18 at the index date.

For the RQ-3 and RQ-4, patients were identified by the first dispensation of a JAKi from January 1 st, 2018 to June 30th, 2019. Cohort entry was defined by the first prescription of JAKi. Only patients with at least six months of observation after cohort entry were included. We excluded patients with less than 10 years of records in the look back period, history of cancer or use of anti-cancer drugs in the look back period, as well as those aged ≤ 18 at index date.

In both the above analyses, patient observation was censored at the end of the study period, loss to follow-up, or death whichever came first.

For the RQ-5, patients were identified by the first prescription of a bDMARD from January 1st, 2014 to December 31st, 2019. Cohort entry was defined by the date of the first prescription of a bDMARD. We included patients with at least one visit in a Tuscan rheumatology ward in the year preceding the cohort entry. We excluded patients with less than 1 year of look back period.

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)

Special population of interest

Immunocompromised

Estimated number of subjects

200

Study design details

Data analysis plan

Descriptive analysis (count, percentages)

Documents

Study results

Final report Leonardo (+ annexes).pdf(1.88 MB)

Data management

ENCePP Seal

Signed checklist for study protocols

ENCePPChecklistfor StudyProtocols (signed).pdf(3.32 MB)

Data sources

Data source(s)

ARS Toscana

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