Advanced treatment of ulcerative colitis using an Italian healthcare administrative database: drug utilization patterns, healthcare resource use and costs The MICHELANGELO study

First published: 04/05/2021

Last updated: 23/05/2024

Study Finalised

Administrative details

EU PAS number

EUPAS40896

Study ID

42877

DARWIN EU® study

No

Study countries

Italy

Study description

This study will describe the population of users of advanced treatments for Ulcerative Colitis in Tuscany (Italy) between January 1st 2015 to December 31st 2019, including history of disease modifying anti rheumatic drugs (DMARDs) use, accesses to Emergency Department (ED), hospitalizations, access to specialist gastroenterology encounters by means of real world data. This study will also analyze health direct costs associated with the management of this population when treated with advanced treatment.

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**

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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

Matteo Fornai

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/04/2021

Actual: 23/04/2021

Study start date

Planned: 26/04/2021

Actual: 26/04/2021

Date of final study report
Planned: 17/05/2021

Actual: 04/09/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Galapagos Biopharma Italy S.r.l.

Study protocol

MICHELANGELO study - protocol.pdf (1.33 MB)

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

This study will describe the population of users of advanced treatments for Ulcerative Colitis in Tuscany (Italy) by means of real world data. This study will also analyze health direct costs (drugs, hospitalizations, ED accesses, specialist encounters) associated with the management of this population when treated with advanced treatment.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ADALIMUMAB

GOLIMUMAB

INFLIXIMAB

TOFACITINIB

VEDOLIZUMAB

Medical condition to be studied

Colitis ulcerative

Population studied

Short description of the study population

Tofacitinib cohort

Inclusion criteria

Patients will be new users of tofacitinib between January 1st, 2015 and December 31st, 2019 AND with a diagnosis OR a co-payemnt exemption code for UC in the lookback period or in the follow up OR a visit in a gastroenterological ward (code: 058) in the year before the index date. Index date will be the date of the first supply. We define new users each subject without supply of tofacitinib in the look-back period (5 years before the index date). Patients will be followed up for one or two years after the index date.

Exclusion criteria

a) Patients with less than 5 years of records in the look back period

b) Patients with less than 1 year of follow-up

c) Patients receiving more than one of the advanced therapy (table 1) at the index date

d) patients with a diagnosis or a co-payment exemption code for Crohn’s disease, rheumatoid arthritis, psoriasis, multiple sclerosis (G35.-), axial spondyloarthritis and ankylosing spondylitis (M45.-), psoriatic arthritis (L40.-),

hidradenitis suppurativa / acne inversa (L73.2), uveitis intermedia, uveitis posterior und panuveitis (H20.-, H30.-) at any time in the look-back period. This criterion will identify only patients with prompt record (clinically relevant conditions)
e) patients aged ≤ 18 at index date
f) patients with records of visits in rheumatology ward (071) or dermatology ward (052) in the 1 year before the index date

Adalimumab cohort
Inclusion criteria
Patients will be new users of an adalimumab between January 1st, 2015 and December 31st, 2019 AND with a diagnosis OR a co-payment exemption code for UC in the lookback period or in the follow up OR a visit in a gastroenterology ward (code: 058) in the year before the index date. Index date will be the date of the first supply. We define new users each subject without supply of adalimumab in the look-back period (5 years before the index date). Patients will be followed up for
one or two years after the index date.

Exclusion criteria
a) Patients with less than 5 years of records in the look back period
b) Patients with less than 1 year of follow-up
c) Patients receiving more than one of the advanced therapy (table 1) at the index date
d) Patients with a diagnosis or a co-payment exemption code for Crohn’s disease, rheumatoid arthritis, psoriasis, multiple sclerosis (G35.-), axial spondyloarthritis and ankylosing spondylitis (M45.-), psoriatic arthritis (L40.-), hidradenitis suppurativa / acne inversa (L73.2), uveitis intermedia, uveitis posterior und panuveitis (H20.-, H30.-) at any time during in the look-back

period. This criterion will identify only patients with prompt record (clinically relevant conditions)
e) patients aged ≤ 18 at index date
f) patients with record of use of oral budesonide (box 1) in the 5 years before cohort entry
g) patients with records of visits in rheumatology ward (071) or dermatology ward (052) in the 1 years before cohort entry

Golimumab cohort

Inclusion criteria
Patients will be new users of an golimumab between January 1st, 2015 and December 31st, 2019 AND with a diagnosis OR a tax exemption code for UC in the lookback period or in the follow up OR a visit in a gastroenterology ward (code: 058) in the year before the index date. Index date will be the date of the first supply. We define new users each subject without supply of golimumab in the lookback period (5 years before the index date). Patients will be followed up for one or two years after the index date.

Exclusion criteria
a) Patients with less than 5 years of records in the look back period
b) Patients with less than 1 year of follow-up
c) Patients receiving more than one of the advanced therapy (table 1) at the index date
d) patients with a diagnosis or a co-payment exemption code for Crohn’s disease, rheumatoid arthritis, psoriasis, multiple sclerosis (G35.-), axial spondyloarthritis and ankylosing spondylitis (M45.-), psoriatic arthritis (L40.-), hidradenitis suppurativa / acne inversa (L73.2), uveitis intermedia, uveitis posterior und panuveitis (H20.-, H30.-) at any time during in the look-back

period. This criterion will identify only patients with prompt record (clinically relevant conditions)
e) patients aged ≤ 18 at index date
f) patients with records of visits in rheumatology ward (071) or dermatology ward (052) in the 1 years before index date

Infliximab cohort
Inclusion criteria
Patients will be new users of an infliximab between January 1st, 2015 and December 31st, 2019 AND with a diagnosis OR a co-payment exemption code for UC in the lookback period or in the follow up OR a visit in a gastroenterology ward (code: 058) in the year before the index date. Index date will be the date of the first supply. We define new users each subject without supply of infliximab in the look-back period (5 years before the index date). Patients will be followed up for one or two year after the index date.

Exclusion criteria
a) Patients with less than 5 years of records in the look back period
b) Patients with less than 1 year of follow-up
c) Patients receiving more than one of the advanced therapy (table 1) at the index date
d) patients with a diagnosis or a co-payment exemption code for Crohn’s disease, rheumatoid arthritis, psoriasis, multiple sclerosis (G35.-), axial spondyloarthritis and ankylosing spondylitis (M45.-), psoriatic arthritis (L40.-), hidradenitis suppurativa / acne inversa (L73.2), uveitis intermedia, uveitis posterior und panuveitis (H20.-, H30.-) at any time during in the look-back period. This criterion will identify only patients with prompt record (clinically relevant conditions)
e) patients aged ≤ 18 at index date

f) patients with record of use of oral budesonide (box 1) in the 5 years before cohort entry
g) patients with records of visits in rheumatology ward (071) or dermatology ward (052) in the 1 years before index date.

Vedolizumab cohort
Inclusion criteria
Patients will be new users of an vedolizumab between January 1st, 2015 and December 31st, 2019 AND with a diagnosis OR a tax exemption code for UC in the lookback period or in the follow up OR a visit in a gastroenterology ward (code: 058) in the year before the index date. Index date will be the date of the first supply. We define new users each subject without supply of infliximab in the look-back period (5 years before the index date). Patients will be followed up for one or two years after the index date.

Exclusion criteria
a) Patients with less than 5 years of records in the look back period
b) Patients with less than 1 year of follow-up
c) Patients receiving more than one of the advanced therapy (table 1) at the index date
d) patients with a diagnosis or a co-payment exemption code for Crohn’s disease, rheumatoid arthritis, psoriasis, multiple sclerosis (G35.-), axial spondyloarthritis and ankylosing spondylitis (M45.-), psoriatic arthritis (L40.-), hidradenitis suppurativa / acne inversa (L73.2), uveitis intermedia, uveitis posterior und panuveitis (H20.-, H30.-) at any time during in the look-back period. This criterion will identify only patients with prompt record (clinically relevant conditions)
e) patients aged ≤ 18 at index date
f) patients with record of use of oral budesonide (box 1) in the 5 years before

index date

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

500

Study design details

Data analysis plan

Descriptive analysis

Documents

Study results

Report MICHELANGELO study (Final).pdf (1.98 MB)

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