Patterns of anti-CGRP mAbs use and triptan consumption before and after anti-CGRP treatment initiation: a descriptive drug utilization study in Tuscany region, Italy

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48413

EU PAS number

EUPAS45727

Study ID

48413

DARWIN EU® study

No

Study countries

☐ Italy

Study description

In 2019, three monoclonal antibodies(mAbs) that target calcitonin gene-related peptide (CGRP),or its receptor,were approved in Italy for both episodic and chronic migraine prophylaxis:erenumab,galcanezumab and fremanezumab. Given the recent introduction of anti-CGRP mAbs on the market, real-world evidence on utilization patterns and the characteristics of patients using anti-CGRP mAbs is still scarce. Therefore, this study aims to re-use routinely collected healthcare data from the administrative database of Tuscany region, Italy, in order to: 1) provide real-world evidence on patients initiating an anti-CGRP mAb, 2) describe the utilization pattern of these medications up to 15 months of follow-up and 3) observe the consumption of triptans, proxy of migraine occurrence, before and after initiation of anti-CGRP therapy. A descriptive, population-based, pharmaco-epidemiological cohort study on the utilization of anti-CGRP mAbs in clinical practice will be performed using the regional administrative datasource of Tuscany, in Italy. Subjects with ≥1 dispensing of any mAb anti-CGRP (ATC N02CD*) reimbursed by the National Health Service between April 1, 2019 to June 30, 2021 and none in the past will be identified and labelled as "new users". The date of the first dispensing will be considered as the cohort entry date. New users will be described in terms of demographic and clinical characteristics. Patients non-persistent to the initial anti-CGRP drug and with a dispensing of an anti-CGRP mAb other the index drug received will be identified and labelled as “discontinuers” and "switchers" respectively. Additionally, patients with ≥ 2 triptan dispensings in the 6 months before cohort entry will be selected . Among them, the mean monthly number of dosage units dispensed during the six months before cohort entry will be compared with that observed in the same population of users within five follow-up windows (i.e. 0-3, 3-6, 6-9, 9-12 and 12-15 months).

Study status

Ongoing

Research institutions and networks

Institutions

Agenzia regionale di sanità della Toscana (ARS)

Italy

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Institution | EU Institution/Body/Agency | ENCePP partner

Headache Centre, Careggi University Hospital, Department of Health Sciences, University of Florence, Italy

Contact details

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Primary lead investigator

Giulia Hyeraci

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/10/2021

Actual: 04/10/2021

Study start date

Planned: 17/01/2022

Actual: 17/01/2022

Date of final study report

Planned: 31/10/2022

Sources of funding

- Other

More details on funding

Agenzia Regionale di Sanità Toscana

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:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

1) To provide real-world evidence on patients initiating an anti-CGRP mAb (i.e. erenumab, fremanezumab, galcanezumab), 2) to describe the utilization pattern of these medications up to 15 months of follow-up and 3) to observe the consumption of triptans, proxy of migraine occurrence, before and after initiation of anti-CGRP therapy.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N02CD01) erenumab

erenumab

(N02CD02) galcanezumab

galcanezumab

(N02CD03) fremanezumab

fremanezumab

Medical condition to be studied

Migraine

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

450

Study design details

Outcomes

Mean monthly number of triptans dosage units dispensed

Data analysis plan

Descriptive analyses will be performed to assess demographic and clinical characteristics of selected anti-CGRP new users. All categorical variables will be shown as patient counts and percentages, while continuous variables will be described by means and standard deviation (SD). New users who discontinued and switched the initial anti-CGRP medication will be reported as the percentage of the total number of patients who started the anti-CGRP treatment. The mean monthly number of dosage units per patient will be used as the measure of triptan consumption before and after initiation of an anti-CGRP treatment. The difference (i.e. Δ) between the observed consumption of triptans during the follow-up window of interest and the baseline period will be reported and the statistical significance will be assessed through the application of the Wilcoxon's test for paired data ($p \leq 0.05$).

Data management

ENCePP Seal

Conflicts of interest of investigators

COI_EUPAS45727.pdf(200.99 KB)

Data sources

Data source(s)

ARS Toscana

Data sources (types)

Administrative healthcare records (e.g., claims)

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