Drug utilization of temozolomide with or without antiepileptic drugs in patients with malignant gliomas in the Tuscany region

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48421

EU PAS number

EUPAS48420

Study ID

48421

DARWIN EU® study

No

Study countries

☐ Italy

Study status

Finalised

Research institutions and networks

Institutions

University of Siena

First published: 01/02/2024

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Institution

University of Pisa

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Institution

University of Pisa Pisa, Azienda Ospedaliera Universitaria Senese Siena, University of Siena Siena

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Andrea Spini

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/07/2022

Actual: 29/07/2022

Study start date

Planned: 29/07/2022

Actual: 29/07/2022

Date of final study report

Planned: 29/07/2022

Actual: 29/07/2022

Sources of funding

- Other

More details on funding

No funding

Study protocol

TMZ_encepp.pdf(1.14 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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Primary objective: To describe the real-world utilization of TMZ with or without antiepileptic drugs for the treatment of patients with malignant gliomas in Tuscany between 2010 and 2021. Secondary objective: To describe the survival of patients using TMZ with or without antiepileptic drugs for the treatment of patients with malignant gliomas in Tuscany between 2010 and 2021.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Descriptive, retrospective observational study

Study drug and medical condition

Name of medicine

TEMODAL

Medical condition to be studied

Glioblastoma

Population studied

Short description of the study population

The study population included patients with malignant gliomas treated with temozolomide with or without antiepileptic drugs identified through Agenzia Regionale della Sanità Toscana (ARS) database between 2010 and 2021.

Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

Other

Special population of interest, other

Patients with malignant gliomas

Estimated number of subjects

1000

Study design details

Outcomes

Drug utilization, Survival

Data analysis plan

Descriptive analyses will be conducted to assess demographic and clinical characteristics of temozolomide users (concomitant/adjuvant) in relation to use of antiepileptic drugs. Continuous variables will be described by means and standard deviation or by median and range. Categorical variables will be described by patient counts and percentages. Characteristics of patients according to concomitant use of antiepileptic drugs will be compared using parametric or non- parametric tests according to distribution of data. A Kaplan Meier curve will be plotted for describing persistence and overall survival during follow- up. Also median overall survival will be calculated.

Data management

Data sources

Data source(s)

ARS Toscana

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

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