Drug Utilization Study of Thiocolchicoside (TCC) containing medicinal products for systemic use in France and Italy: an electronic medical records databases study

First published: 24/09/2015

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11081

Study ID

33991

DARWIN EU® study

No

Study countries

France

Italy

Study description

The aim of this drug utilization study is to characterisepprescribing practices of TCC-containing medicinal productsduring typical clinical use in representative groups ofprescribers and assess main reasons for prescription.The study objectives are:• To describe the demographic and clinicalcharacteristics of the treated patients (i.e. age andgender, co-medications, pregnancy, contraceptive use,lactation)• To describe for which indication TCC is prescribed inroutine clinical practice (overall and by age/gender)• To describe the average duration of treatment episodesand the daily doses prescribed according to the routeof administration• To compare patients characteristics pre- and postimplementationof RMMs

Study status

Finalised

Research institutions and networks

Institutions

Real World Evidence Solutions, IMS Health

France

First published: 06/09/2011

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Institution | Other

Multiple centres: 100 centres are involved in the study

Contact details

Study institution contact

Intissar Bourahla ibourahla@fr.imshealth.com

Study contact

ibourahla@fr.imshealth.com

Primary lead investigator

Intissar Bourahla

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/04/2015

Actual: 02/04/2015

Study start date

Planned: 01/09/2015

Actual: 30/06/2017

Data analysis start date

Planned: 04/09/2017

Date of interim report, if expected
Planned: 31/12/2017

Date of final study report
Planned: 31/12/2019

Actual: 26/11/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Marketing Authorization Holder

Study protocol

Thiocolchicoside-epi-pass-dus-study-report-final -26NOV19.pdf (9.69 MB)

Thiocolchicoside_DUS protocol 5.0_02 MAR 2017_bis_clean_FINAL_with annexes.pdf (1.8 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To characterise prescribing practices of TCC-containing medicinal products during typical clinical use and assess main reasons for prescription.To describe the demographic and clinical characteristics of the treated patientsTo describe the average duration of treatment episodes and the daily doses prescribed according to the route of administration

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

THIOCOLCHICOSIDE

Population studied

Short description of the study population

All patients with at least one prescription of Thiocolchicoside (TCC)-containing medicinal products for systemic use in the selected databases during the study periods, i.e. before (baseline: year 2013) or after the implementation of the minimization measures

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Age groups

- 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)

Estimated number of subjects

50000

Study design details

Data analysis plan

A descriptive analysis of TCC utilization will be performed:Indication,Dosage,Duration, Therapeutic regimen: mono-therapies or adjuvant therapies (use of TCC along with other pre- specified co-medications).Description of drug utilization by age and gender Description of prevalent and incidence

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)

Longitudinal Patient Data - France

Longitudinal Patients Database - OMOP

Data sources (types)

Electronic healthcare records (EHR)

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