Evaluation of the Effectiveness of Risk Minimisation Measures: A Joint PASS Survey among Health Care Professionals to Assess their Knowledge and Attitudes on Prescribing Conditions of Thiocolchicoside containing Medicinal Products for Systemic Use in France, Greece, Italy and Portugal

First published: 03/12/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/23054

EU PAS number

EUPAS11765

Study ID

23054

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Greece
- [ ] Italy
- [ ] Portugal

Study description

Thiocolchicoside (TCC) is a semi-synthetic sulfurated colchicoside derivative with a muscle relaxant pharmacological activity, used in the management of non-specific low back pain. TCC is indicated as adjuvant treatment of painful muscular contractures in acute spinal pathology, in adults and adolescents from 16 years onwards. The benefits of TCC containing medicinal products are recognised in clinical practice, and they are widely used by prescribers in the concerned Member States (see Annex 3). An Article 31 referral on thiocolchicoside-containing medicinal products for systemic use was initiated in February 2013. The CHMP has concerns with regard to the potential genotoxicity of thiocolchicoside-containing medicinal products for systemic use. Within the context of minimization measures as per European Commission decision dated 17 January 2014, including a Dear Healthcare Professional Communication, changes to the SmPC, Labelling and Package Leaflet. As per EMA request the present survey will be conducted in complement to a Joint Drug Utilization Study.

Study status

Finalised

Research institutions and networks

Institutions

Real World Evidence Solutions, IMS Health

France

First published: 06/09/2011

Last updated: 20/08/2024

Institution | Other

Contact details

Study institution contact

Toussi Massoud

Study contact

mtoussi@fr.imshealth.com

Primary lead investigator

Toussi Massoud

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/11/2015

Actual: 20/11/2015

Study start date
Planned: 01/04/2016

Actual: 01/02/2017

Date of final study report
Planned: 31/01/2017

Actual: 01/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Acarpia services farmaceuticos Lda, Alter laboratoire, Angelini, Angenerico SpA, Arrow Generiques, Biogaran, Cristers, Daiichi Sankyo, Doc Generici, Dompe Farmaceutici SpA, EG labo, EG SpA, Epifarma Srl, Farmaceutici Caber SpA, Generis Farmaceutica, Korangi, Laboratorio Farmaceutico CT Srl, MDM, Mylan, Sandoz, Sanofi Aventis Groupe, SF Group Srl, SPA, Teofarma Srl, Union Health Srl.

Study protocol

1078739-Thiocolchicoside - Survey Protocol_08 Augut2016 _LAST.pdf(1.89 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 type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

Whether the dear healthcare professionals communication (DHPC) and educational materials (EM), implemented as risk minimisation measures (RMM), were effective to ensure:- correct knowledge of physicians about prescribing conditions and safe use when prescribing systemic thiocolchicoside- appropriate attitude when prescribing systemic thiocolchicoside

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

General practitioners and specialists (rheumatologists and orthopedists / orthopedic surgeons) who prescribed systemic thiocolchicoside within the last 12 months.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

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

Pregnant women

Estimated number of subjects

600

Study design details

Outcomes

to measure the effectiveness of the DHPC and EM, implemented as part of RMM, by ascertaining the proportion of targeted physicians who understood and implemented the latest prescribing conditions and safety information about systemic thiocolchicoside provided in the DHPC and EM. Specific objectives were to evaluate the proportion of physicians who:• prescribe systemic colchicoside only as adjuvant treatment of painful muscle contractures associated with acute spinal pathology in adults and in adolescents from 16 years onwards.• do not prescribe systemic thiocolchicoside for long-term treatment of chronic conditions.• follow the recommendations regarding doses

Data analysis plan

The statistical analysis will be conducted using the SAS® softwareV9.3 on Windows™ (SAS Institute, North Carolina, USA).Results will be presented, overall and at country level per specialty. Continuous variables will be described by the number of valid cases and missing data, mean, standard deviation, median, Q1, Q3, minimum, and maximum. No missing data will be replaced. Categorical variables will be described as the total number and relative percentage per category. Confidence intervals of 95% will be calculated when relevant. Calculations will first be performed on raw data per specialty, and weighted according to the real proportion of targeted physicians in each country to accurately reflect the population the survey seeks to measure.

Possible selection bias will be assessed by comparing the distributions of available characteristics (e.g. region, age, gender, type of practice and specialty) between respondent and non-respondent physicians.

Documents

Study results

TCC report abstract.pdf(149.06 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Survey among healthcare professionals

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

Yes