# 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

**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 mtoussi@fr.imshealth.com

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 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

## 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 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