SURVEILLANCE STUDY OF PHOTOCONTACT DERMATITIS LEADING TO HOSPITALIZATION IN EUROPE WITH A SPECIAL FOCUS ON TOPICAL KETOPROFEN AND OTHER TOPICAL NSAIDs, INCLUDING EVALUATION OF SEVERE PHOTOSENSITIVITY REACTIONS (KETO1)

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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/28279

EU PAS number
EUPAS2679

Study ID
28279

DARWIN EU® study
No

Study countries
Czechia
France
Italy

Study description
Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) with analgesic and antipyretic effects. Topical ketoprofen is used in more than 70 countries worldwide. In spite of having been associated with photocontact dermatitis, limited data are available on incidence rate of reactions leading to hospitalization and on risk factor for the reaction.As requested by EMA in 2010 (procedure No. EMEA/H/A-107/1259) and to better evaluate the risk and benefit profile of topical ketoprofen, an epidemiologic case-control study was proposed focusing on severe photosensitivity reactions leading to hospitalization and assessing risks linked to the use of topical ketoprofen and other topical NSAIDs. The study will be conducted on a Europe-wide scale and requires that clear assumptions are made about exposure rates, criteria to define cases of severe photosensitivity, and incidence of severe photosensitivity reactions.To assess the feasibility of such a case-control study before embarking into a Europe-wide large-scale endeavor, a pilot study will be conducted focusing on incidence rates of severe photosensitivity reactions leading to hospitalization, and prevalence of exposure to topical ketoprofen among controls. These pieces of information will be used to estimate the sample size and the statistica power of the case control study. The pilot phase will also address methodological issues granting validity to the study, including standardization of diagnostic criteria and comparison between exposure among controls and exposure in the underlined at risk population so that indirect methods to assess attributable risks could be applied in the case control study.Centers in three geographic areas, intended to represent the variety of Europe in terms of different rates of exposure to topical NSAIDs and of incidence of photosensitivity reactions, will participate to this pilot study (Lombardy region, Paris metropolitan area, Prague metropolitan area).

Study status
Finalised

Research institution and networks

Institutions

Centro Studi GISED
Italy
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Institution
Not-for-profit
ENCePP partner

UPEC-Université Paris-Est Créteil Val de Marne Paris, France, 2nd Medical School, Charles University Prague, Czech Republic

Networks

REACT

Contact details

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Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
24/04/2012

Study start date
Planned:
01/09/2012
Actual:
02/10/2012

Data analysis start date
Planned:
15/11/2012
Actual:

15/11/2012

Date of interim report, if expected
Planned:
01/12/2012
Actual:
06/12/2012

Date of final study report
Planned:
30/04/2013
Actual:
05/11/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Menarini, Bayer SpA, Cyathus, Dompè SpA, EG SpA, JSC Grindeks, Hisamitsu Ltd, Istituto Biochimico Italiano, Italfarmaco SpA, Pierre Fabre, Sanofi-Aventis, Sandoz

Study protocol

Ketoprofen_-_Pilot_phase_Protocol_F.1_11-06-2012[1].pdf(333.67 KB)

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:
Disease /health condition
Human medicinal product

Study type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness
Drug utilisation

Data collection methods:
Primary data collection

Main study objective:
-to assess the prevalence of exposure to topical NSAIDs in a sample of hospital controls selected as in case-control studies-to develop strict diagnostic criteria for severe photosensitivity-to estimate the incidence of severe photosensitivity leading to hospitalization in selected sampling areas.

Study Design

Non-interventional study design
Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
100000096894
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS
100000096930
ketoprofen

Medical condition to be studied
Photosensitivity reaction

Population studied

Short description of the study population
Patients with following criteria were included:
1. Age 18-74 years

2. Consecutive patients of both gender admitted for any of the following acute conditions or elective procedures:
- Acute infection or inflammation*: pneumonia, gastroenteritis, cellulitis, pancreatitis (first episode), otitis media, peritonitis, epididymitis, abscess, meningitis, encephalitis, pelvic inflammatory disease
- Trauma (not related to alcohol or osteoporosis): fractures, sprains/strains, dislocations
- Acute abdominal emergencies*: appendicitis, strangulated hernia, rupture or torsion of an ovarian cyst, acute abdominal pain, ectopic pregnancy, thrombophlebitis (males only, first episode)
- Spontaneous pneumothorax
- Alternative diagnoses (when the previous ones are not available): hernias, hallux valgus, cosmetic surgery, deviated nasal septum
* Diagnosis in this group are not all-inclusive, but rather examples of appropriate conditions
- Signed informed consent

Age groups
Adults (18 to < 46 years)
Adults (46 to < 65 years)
Adults (65 to < 75 years)

Estimated number of subjects
900

Study design details

Outcomes
-the estimate of prevalence of exposure to topical ketoprofen in the general population. A secondary outcome will be the prevalence of exposure to other topical NSAIDs -The definition of a standard operative procedure for the identification and diagnosis of photosensitivity reactions-The estimate of the incidence of photosensitivity reactions in selected European areas

Data analysis plan
Row and age-standardized prevalence rates together with their 95% confidence intervals (CI) will be calculated for NSAIDs exposure as well as for other variables of interest. Stratification by gender and country will be used for general descriptive statistics as well as for exposure rates. Differences among categories will be tested with Pearson’s chi-squared test or Fisher’s exact test for nominal variables and by Mann-Whitney U test for continuous variables. To estimate possible selection biases in the collection of the sample, a comparison of general characteristics of individuals undergoing the interview and, in particular, their exposure rates to topical NSAIDs, with the expected distribution based on demographic and general sales data obtained from individual areas will be made. Whenever it will be possible risk estimate for exposure will be derived from odds ratio calculation. Multiple logistic regressions will be used to adjust risk estimates for potential confounders.

Documents

Study, other information
Keto1_vers F1 Questionnaire 11-06-2012.pdf(457.2 KB)

Data management

ENCePP Seal

Composition of steering group and observers
Composition of the Steering Committee.pdf(108.05 KB)

Data sources

Data sources (types)
Other

Data sources (types), other
Prospective patient-based data collection

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