EMA Self-Controlled Case Study of Fluoroquinolones and Retinal Detachment in The Health Improvement Network database

First published: 04/06/2014

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Study Finalised

Administrative details

EU PAS number

EUPAS6708

Study ID

15151

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Further to it's assessment of a signal of risk of retinal detachment (RD) in association with use of systemic fluoroquinolones (FQ), the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency (EMA) recommended at its April 2013 meeting that the EMA perform a Self-Controlled Case Study on RD and FQ in The Health Improvement Network (THIN) database of electronic health records. The SCCS methodology can be applied to those patients who have experienced the outcome of interest and have been exposed to risk factor(s) over some period of time. The method considers how frequently the outcome occurs during exposure compared to non-exposed times.All patients in THIN who had a code for RD and for a FQ in the interval from 1 Jan 1990 to 31 Dec 2012 were considered for the study. The study period began once a patient has attended a THIN practice for at least one year and any record of RD during this screening period resulted in exclusion from the study.The risk period was calculated using information on the prescribed quantity and the dosage regimen from the THIN dosage file. The primary analysis considered the risk period to be only those days when the patient was judged to be taking the FQ. When there was insufficient information to calculate the risk period it was imputed using the modal calculated value for the particular product prescribed. A sensitivity analysis used the minimum and maximum credible values for each product and the number and proportion of imputed values has been reported.Other risk factors for retinal detachment included in the model were traumatic events which encompassed cataract or other ocular surgery, eye infections, ocular trauma and head or neck injuries, exposure to corticosteroids, age and season.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

European Medicines Agency

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jim Slattery

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/04/2013

Actual: 30/04/2013

Study start date
Planned: 01/05/2013

Actual: 01/05/2013

Date of final study report
Planned: 02/06/2014

Actual: 02/06/2014

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

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:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

To determine whether there is an increased risk of retinal detachment in patients treated with systemic (fluoro)quinolones

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Self-controlled case series

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J01M) QUINOLONE ANTIBACTERIALS

QUINOLONE ANTIBACTERIALS

Medical condition to be studied

Retinal detachment

Population studied

Short description of the study population

All patients in THIN who had a code for retinal detachment (RD) and for a fluoroquinolones (FQ) in the interval from 1 Jan 1990 to 31 Dec 2012

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

Other

Special population of interest, other

Retinal detachment patients

Estimated number of subjects

2.584

Study design details

Outcomes

Retinal detachment, To determine whether discrepancies between the studies can be explained by failure of assumptions underlying the basic SCCS model.

Data analysis plan

The primary risk estimation analysis was carried out both in SAS and in STATA using the methods available from the Open University http://statistics.open.ac.uk/sccs/sas.htm.

Documents

Study results

EMA_FQ_RD_SCCS.pdf (662.64 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 source(s)

THIN® (The Health Improvement Network®)

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