Risk of tendon rupture with systemic fluoroquinolone exposure: nested case-control study

First published: 06/09/2017

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS20892

Study ID

29762

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Nested case control study to quantify the risk of tendon rupture with systemic fluoroquinolone exposure in primary care.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Daniel Morales

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 03/04/2017

Actual: 03/04/2017

Study start date
Planned: 10/04/2017

Actual: 10/04/2017

Data analysis start date
Planned: 17/04/2017

Actual: 17/04/2017

Date of final study report
Planned: 29/01/2018

Actual: 01/11/2018

Sources of funding

- EMA

Study protocol

EUPAS20892.protocol.pdf (63.9 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

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

Data collection methods:

Secondary use of data

Main study objective:

To quantify the risk of tendon rupture associated with systemic oral fluroquinolone exposure from primary care

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J01MA) Fluoroquinolones

Fluoroquinolones

Medical condition to be studied

Tendon rupture

Population studied

Short description of the study population

Adults aged 18 years or over identified from THIN database between January 1, 1999 and December 31, 2015 issued at least one prescription of co-amoxiclav or fluoroquinolone antibiotic product with a systemic route of administration.

Age groups

- 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

40000

Study design details

Outcomes

Tendon rupture, Interaction with systemic corticosteroid therapy

Data analysis plan

From a cohort of patients administered antibiotic therapy, cases of tendon rupture will be matched to controls on age, gender and calendar time using risk set sampling. Odds ratios will be calculated for the association between current fluoroquinolone exposure and risk of any tendon rupture and the most frequent types of tendon rupture, using pre-specified risk windows. Adjustment for confounders including body mass index, comorbidity (charslon index), age, smoking status, prior history of tendon rupture and oral corticosteroid therapy will be undertaken. Interaction between fluoroquinolone exposure and oral corticosteroid therapy will be undertaken on the multiplicative scale.

Documents

Study results

EUPAS20892.pdf (600.48 KB)

Study publications

Morales DR, Slattery J, Pacurariu A, Pinheiro L, McGettigan P, Kurz X. Relative...

Morales DR, Flynn R, Kurz X. Addendum to: Relative and Absolute Risk of Tendon ...

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

Unknown