

Fluoroquinolones and the risk of tendon injury: a systematic review and meta-analysis

First published: 16/04/2019

Last updated: 13/09/2021

Study

Finalised

Administrative details

EU PAS number

EUPAS29426

Study ID

29427

DARWIN EU® study

No

Study countries

 Portugal


Study status

Finalised

Research institutions and networks

Institutions

Pharmacovigilance and Pharmacoepidemiology, AIBILI

 Portugal

First published: 11/04/2011

Last updated: 01/09/2023

Institution

Educational Institution

Not-for-profit

ENCePP partner

Contact details

Study institution contact

Carlos Alves calves@aibili.pt

Study contact

calves@aibili.pt

Primary lead investigator

Carlos Alves

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2018

Actual: 01/04/2018

Study start date

Planned: 01/07/2018

Actual: 01/07/2018

Date of interim report, if expected

Planned: 08/02/2019

Actual: 08/02/2019

Date of final study report

Planned: 05/04/2019

Actual: 05/04/2019

Sources of funding

- No external funding

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:

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:

Assess the risk of tendon injuries associated with the use of systemic fluoroquinolones, as well as to explore risk variations due to risk factors, study designs and methodological quality of included studies.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J01MA) Fluoroquinolones

Fluoroquinolones

Medical condition to be studied

Tendon injury

Population studied

Short description of the study population

Patients of all ages and genders treated with fluoroquinolones.

Age groups

- 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

Renal impaired

Estimated number of subjects

1345580

Study design details

Outcomes

Assess the risk of tendon injuries associated with the use of systemic fluoroquinolones.

Data analysis plan

A meta-analysis will be performed by pooling odds ratios (ORs) with their 95% confidence intervals (CIs), using the DerSimonian and Laird random-effects model. If the studies presented more than one risk estimate, the most adjusted one would be used. The effect size estimates available for the shortest time intervals between fluoroquinolones prescription and tendon injury diagnosis or treatment will be used in the overall risk estimate. The I2 statistic test will be used to assess heterogeneity between studies. An I2 estimate > 50% will be considered indicative of substantial heterogeneity. The publication bias will be visually examined by a funnel plot and statistically evaluated by Egger's regression asymmetry test. Stata (version 13.1) will be used to perform statistics.

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

Estimated obtained in previously conducted studies.

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