The risk of musculoskeletal adverse outcomes after treatment with endocrine blocking treatments for breast cancer (MSKAI)

First published: 09/12/2020
Last updated: 22/02/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/40382

EU PAS number
EUPAS38362

Study ID
40382

DARWIN EU® study
No

Study countries
Germany
Spain
United Kingdom
United States

Study description
To evaluate the comparative risk of musculoskeletal side effects following treatment with tamoxifen versus aromatase inhibitors

Study status
Ongoing

Research institution and networks

Institutions

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

United Kingdom
First published: 01/02/2024
Last updated 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

IQVIA

United Kingdom
First published: 12/11/2021
Last updated 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain
First published: 05/10/2012
Last updated 23/02/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

IDIAPJGol Spain, NDORMS, University of Oxford UK

Networks

Observational Health Data Sciences and Informatics (OHDSI) Network

First published: 01/02/2024
Last updated 01/02/2024

Network

European Health Data Evidence Network (EHDEN)

Netherlands
First published: 01/02/2024
Last updated 11/06/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Lane Jennifer

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
02/11/2020

Study start date
Planned:
14/12/2020
Actual:
14/12/2020

Data analysis start date
Actual:

23/03/2020

Date of final study report
Planned:
01/07/2021

Sources of funding

- Non for-profit organisation (e.g. charity)

More details on funding

MRC, NIHR, Versus Arthritis

Study protocol

MSK_AI_Protocol_1.4 for EU PAS.pdf(905.49 KB)

MSK_AI_Protocol_1.5 for EU PAS.pdf(905.41 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 type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness
Disease epidemiology

Main study objective:
The aim of this study is to assess the comparative risk of musculoskeletal adverse events in post menopausal women taking of tamoxifen (TMX) versus Aromatase Inhibitors (AI) used in the treatment of breast cancer.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(L02BA01) tamoxifen
(L02BG06) exemestane
(L02BG04) letrozole
(L02BG03) anastrozole
(L02BG05) vorozole

Medical condition to be studied
Breast cancer female

Additional medical condition(s)
Osteoarthritis, Carpal tunnel syndrome, tendinopathy

Population studied

Age groups
Adults (46 to < 65 years)
Adults (65 to < 75 years)
Adults (75 to < 85 years)
Adults (85 years and over)

Estimated number of subjects
500000

Study design details

Outcomes
comparative risk of developing carpal tunnel syndrome, osteoarthritis and tendinopathies, If sufficiently powered, this study aims to assess the comparative risk of musculoskeletal adverse events in those taking non-steroidal AIs (NSAIs) versus steroidal AIs (SAIs)

Data analysis plan
New user design within a comparative cohort analysis of tamoxifen versus aromatase inhibitors, with the hazards of outcome during the follow-up periods compared using a univariate Cox proportional hazards model conditioned on the PS adjustment with treatment allocation as the sole explanatory variable

Data management

Data sources

Data source(s)
Clinical Practice Research Datalink
The Information System for Research in Primary Care (SIDIAP)
Ambulatory EMR - OMOP

Data source(s), other
CPRD, SIDIAP, Electronic Medical Records Data (Ambulatory) - US

Data sources (types)
Administrative data (e.g. claims)
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