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

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 institutions 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: 23/05/2025

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: 04/08/2025

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

tamoxifen

(L02BG06) exemestane

exemestane

(L02BG04) letrozole

letrozole

(L02BG03) anastrozole

anastrozole

(L02BG05) vorozole

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

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)

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 healthcare records (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