The risk of developing prostate cancer in entacapone and levodopa/DDCI users compared to levodopa/DDCI users without entacapone - A nation-wide retrospective register-based study

First published: 29/05/2012

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS2612

Study ID

14806

DARWIN EU® study

No

Study countries

Finland

Study description

The purpose of the study is to evaluate whether treatment with entacapone as add-on to levodopa/DDCI increases the risk of developing prostate cancer when comparing to treatment without entacapone as add-on to levodopa/DDCI among male PD patients in Finland.

Study status

Finalised

Research institutions and networks

Institutions

EPID Research Oy

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Pasi Korhonen

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/02/2011

Actual: 21/02/2011

Study start date
Planned: 16/05/2011

Actual: 01/12/2011

Date of final study report
Planned: 31/10/2012

Actual: 25/06/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Orion Corporation Orion Pharma

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

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:

The primary objective of this study is to compare the incidence rates of developing prostate cancer between group 1 and group 2 where group 1 = treatment with levodopa/DDCI with entacapone +/- DA and/or MAO-B inhibitor, and group 2 = treatment with levodopa /DDCI without entacapone +/- DA and/or MAO-B inhibitor.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective cohort study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N04BA03) levodopa, decarboxylase inhibitor and COMT inhibitor

levodopa, decarboxylase inhibitor and COMT inhibitor

(N04BX02) entacapone

entacapone

Medical condition to be studied

Parkinson's disease

Population studied

Short description of the study population

Population included all males in Finland who have purchased at least one prescription of any Parkinson’s disease medication including entacapone, levodopa/DDCI, monoamine oxidase B (MAO-B) inhibitors, and dopamine agonists (DA) during 1998 – 2009.

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

Other

Special population of interest, other

Patients with Parkinson's disease

Estimated number of subjects

16000

Study design details

Outcomes

Time from the start of follow-up to the first prostate cancer detected. Time from the start of follow-up to death caused by prostate cancer.

Data analysis plan

Comparisons between the treatment groups will be performed by means of hazard ratios (HRs). The HR estimates with 95% CIs will be estimated using the conventional Cox’s proportional hazards model with adjustments for relevant baseline variables and time-dependent variables. The following variables will be considered as potential confounders in these analyses: age group, time since PD diagnosis, PD and BHP treatment history, hospital district, concurrent use of BHP treatments (e.g. finasteride), duration of earlier levodopa/DDCI treatment, and recent changes in PD add-on treatments.

Documents

Study results

ER_9411_StudyReport_Version_1_0_signed.pdf (1.35 MB)

Study publications

Korhonen P, Kuoppamäki M, Prami T, Hoti F, Cristopher S, Ellmèn J, Aho V, Vahte...

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.

Signed code of conduct

ENCePP_Annex3_DeclarationSignaturePage.pdf (902.67 KB)

Signed code of conduct checklist

ENCePP_Annex2_Checklist.pdf (169.6 KB)

ENCePP_Annex2_ChecklistSignaturePage.pdf (640.72 KB)

Signed checklist for study protocols

ENCePPChecklistforStudyProtocolsSignaturePage.pdf (855.25 KB)

EUPAS2612-2625.pdf (193.4 KB)

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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