

Longitudinal Analyses of Body Mass Index and Risk of Parkinson's Disease in 2 million people over 2 decades (BMI and Parkinson's disease)

First published: 04/04/2018

Last updated: 02/07/2024

Study

Ongoing

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/23455>

EU PAS number

EUPAS23454

Study ID

23455

DARWIN EU® study

No

Study countries

Spain

United Kingdom

Study description

Previous research suggests that people who are overweight or obese may have a higher risk of developing Parkinson's disease than people with normal weight, while other studies show no such association. The objective of this study is therefore to investigate the association between BMI and risk of Parkinson's disease. A cohort will be derived from CPRD of people aged 40 years or older with a first BMI recording between 1992 and 2007. People with a prior record of Parkinson's disease or dementia will be excluded. Incidence rates of Parkinson's disease will be calculated for each BMI category using Poisson

regression, adjusting for differences in patient characteristics and allowing for competing risks with a novel approach. This study will provide information from a very large number of people (2 million) with a sizeable amount of follow-up data in a representative sample. The findings will therefore provide important information to help clarify the relationship between BMI and Parkinson's disease to inform preventative and therapeutic strategies for Parkinson's disease.

Study status

Ongoing

Research institution and networks

Institutions

OXON Epidemiology

Spain

United Kingdom

First published: 06/12/2010

Last updated

15/03/2024

Institution

Non-Pharmaceutical company

Laboratory/Research/Testing facility

ENCePP partner

Pharmacoepidemiology Group, London School of Hygiene & Tropical Medicine (LSHTM)

United Kingdom

First published: 19/04/2010

Last updated

18/06/2012

Institution

ENCePP partner

Educational Institution

OXON Epidemiology

Spain

United Kingdom

First published: 06/12/2010

Last updated

15/03/2024

Institution

Laboratory/Research/Testing facility

Non-Pharmaceutical company

ENCEPP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned:

20/07/2016

Actual:

20/07/2016

Study start date

Planned:

20/07/2016

Actual:

20/07/2016

Data analysis start date

Planned:

15/09/2016

Actual:

15/09/2016

Date of final study report

Planned:

17/09/2018

Sources of funding

- Other

More details on funding

No 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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Main study objective:

The primary objective is to estimate the age-specific associations between BMI and Parkinson's disease. Secondary objectives are to assess the shape of the association and Identify potential modifiers and confounders of the risk. The results will be usable for disease prediction models, patient management, the planning of trials, and help in hypotheses of pathophysiological mechanisms of PD

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Obesity

Parkinson's disease

Population studied

Short description of the study population

2 million patients followed up over 2 decades. Underweight (< 20 kg/m²): 106,716 people
Healthy weight (20-24.9 kg/m²): 629,126 people Overweight (25-29.9 kg/m²): 727,339
people Obese (? 30 kg/m²): 489,406 people With a median follow-up of 9.3 years, PD
occurred in 11,616 people.

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

2000000

Study design details

Outcomes

Parkinson's disease

Data analysis plan

We compared rates of PD across categories of BMI using Poisson regression models. Standardised incidence rates and rate ratios were either adjusted for age (in five-year bands) and sex, or further adjusted for the following covariates, measured at the time of index BMI. We used age at diagnosis, updating the data as people moved through the age categories during follow-up. Incidence rates were standardised to the age and sex distribution of the overall study population. We performed analyses to investigate whether the association between BMI and PD varied depending on the time from the index BMI measurement. We calculated the cumulative incidence of PD using the Kaplan-Meier estimator, with age as the underlying time scale. We performed a sensitivity analysis to investigate whether our findings could be reasonably explained by competing risks using a novel approach under a hypothetical scenario and using matching

Documents

Study, other information

[BMI and PD_poster ICPE_2016.pdf](#)(465.51 KB)

Study publications

Iwagami, M., Qizilbash, N., Gregson, J., Douglas, I., Johnson, M., Pearce, N., ...

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

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

No