Pain characteristics of patients recommended total knee arthroplasty due to painful osteoarthritis – a cross-sectional analysis of depersonalized real-world data of the German Pain e-Registry to evaluate the bio-psycho-social profile/burden of patients participating in an interdisciplinary second opinion program prior surgery (PACE-1)

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Study Finalised

Administrative details

EU PAS number

EUPAS107501

Study ID

107502

DARWIN EU® study

No

Study countries

☐ Germany

Study description

The objective of this study is to perform a comprehensive real-world evidence cross-sectional evaluation of the bio-psycho-social profile (i.e. patient burden) of patients with end-stage painful osteoarthritis of the knee and a given recommendation for total knee arthropasty (TKA) who took the opportunity of the second opinion (SO) program of the IMC to reevaluate the rationality and to improve the risk-benefit probability of the surgical intervention – based on data gathered via the German Pain e-Registry as part of the standardized interdisciplinary evaluation process IVZ-G according to the standards defined in the quality assurance agreement for specialized pain management (QST, § 138 SGB V) and following the recommendations of the German Pain Association and the German Pain League.

Study status

Finalised

Research institutions and networks

Institutions

O.Meany-MDPM

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Institution

Contact details

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Primary lead investigator

Michael Ueberall

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/07/2023

Actual: 14/07/2023

Study start date

Planned: 17/07/2023

Actual: 17/07/2023

Data analysis start date

Planned: 21/08/2023

Actual: 21/08/2023

Date of final study report

Planned: 03/11/2023

Actual: 03/11/2023

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Grunenthal, Institute of Neurological Sciences

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

Main study objective:

The primary objective of this exploratory study is to identify characteristic biopsychosocial features of patients with pOAK who are referred for TKA.

Study Design

Non-interventional study design

Cross-sectional

Population studied

Age groups

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)

Estimated number of subjects

2108

Study design details

Data analysis plan

Data analyses will be performed for the complete set of anonymized data provide by the GPeR according to the given in- and exclusion criteria (see below). Descriptive statistical analyses will be performed as reported. For continuous variables, descriptive statistics will be summarized by the number of patients (n), the mean, standard deviation (SD), 95% confidence intervals (95%-CI) of the mean, median, and range (minimum – maximum) values. For categorical and ordinal variables data will be summarized by frequency number (n), percentage (%) and (where appropriate) adjusted percentage (a%) of participants in each category, incl. 95% confidence intervals. As this project follows is a purely exploratory/descriptive approach, no confirmatory procedures will be applied. Only one data lock is planned for this study, when the anonymized data sets will be completely extracted from the GPeR.

Data management

Data sources

Data source(s), other

German Pain e-Registry Germany

Data sources (types)

Disease registry

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