Prevalence of drug-induced constipation and severity of associated biopsychosocial effects in patients with nonmalignant pain. A cross-sectional review of depersonalized data from the German Pain e-Registry (DRIP)

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Study Finalised

Administrative details

EU PAS number

EUPAS42286

Study ID

42287

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Constipation is a frequent medical problem and affects, depending on methodological and geographic differences, up to 28% of the general population. Epidemiological studies showed that the prevalence of constipation increases with age, is higher in women compared to men and severity as well as time course are very variable. Likewise are the correlating effects on quality of life and well-being variable. Drug induced constipation (DIC) is one of the most frequent adverse reactions and a frequent reason for (co-)morbidity in otherwise healthy persons as well as in pain patients in all parts of the world. Reports on DIC in pain patients largely address opioid-induced constipation (OIC) as one aspect of opioid-induced bowel dysfunction. However, DIC also occurs in response to non-opioid analgesics and pain related co-medication such as non-steroidal anti-inflammatory drugs (NSAIDs), antidepressants (ADDs), anticonvulsants (AEDs)and others. Furthermore, recent studies in elderly non-pain patients reported a correlation between occurrence and severity of constipation and the overall number of drugs used. This raises questions on a potential impact of analgesic polypharmacy on the prevalence and the biopsychosocial consequences of constipation in patients with chronic nonmalignant pain (NMP), who frequently receive a polymedication with or without opioid analgesics. To gain further insight into the prevalence and biopsychosocial consequences of DIC in patients with NMP we evaluated anonymized real-world data derived from routine medical care in pain centers within the German Pain e-Registry (GPeR), a national web-based registry developed in cooperation with the German Pain Association (Deutsche Gesellschaft für Schmerzmedizin) and the German Pain League (Deutsche Schmerzliga).

Study status

Finalised

Research institutions and networks

Institutions

Institute for Neurological Sciences (IFNAP)

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Institution

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/03/2021

Actual: 02/03/2021

Study start date
Planned: 02/03/2021

Actual: 02/03/2021

Data analysis start date
Planned: 03/05/2021

Actual: 03/05/2021

Date of final study report
Planned: 23/07/2021

Actual: 23/07/2021

Sources of funding

- Other

More details on funding

IFNAP - private 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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Safety study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Tolerability

Data collection methods:

Secondary use of data

Main study objective:

To assess the influence of drug-induced constipation on pain, pain-related disabilities in daily life, and further biopsychosocial factors such as quality-of-life, depression, anxiety, mood, and overall wellbeing

Study Design

Non-interventional study design

Cohort

Cross-sectional

Other

Non-interventional study design, other

Retrospective registry analysis

Study drug and medical condition

Medical condition to be studied

Pain

Additional medical condition(s)

Chronic nonmalignant pain

Population studied

Short description of the study population

Patients with chronic nonmalignant pain (NMP), who frequently receive a polymedication with or without opioid analgesics.

Age groups

Children (2 to < 12 years)

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)

Estimated number of subjects

150000

Study design details

Outcomes

The primary end point was the proportion of patients with five or more serious findings within the nine properties evaluated (based on the following cut-off ranges: a) pain intensity, b) daily functioning, c/d) physical/mental quality-of-life, e) depression, f) anxiety, g) stress, h) wellbeing, and i) quality-of-life impairment by pain.

Data analysis plan

Biometric analyses will beperformed using the descriptive procedures suitable for the respective data format. Mean data will be presented with standard deviation or 95% confidence intervals (CI), proportions expressed in percent (%) and if necessary, adjusted for the number of patients with available data (a%). For statistical between cohort comparisons Pearson’s chi-square test and Wilcoxon’s signed rank test will be performed using a two-sided significance level of 0.05. All comparisons will be exploratory, therefore neither significance levels will be adjusted for multiplicity nor confirmatory analyses performed. All analyses will be conducted with PASW Statistics version 18.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

German Pain e-Registry

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