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Looking back at health data collected over 9 years to assess the long term effects of using opioids to treat chronic back pain

Submission date
24/05/2020

Recruitment status
No longer recruiting

Registration date
28/05/2020

Overall study status
Completed

Last Edited
20/07/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Spinal pain is the leading worldwide cause of years lived with chronic pain and disability. While opioids are well documented as an effective short-term pain-relieving medication, more than a few weeks of treatment may result in a reduced effect of pain relief as well as the development of addictive behaviour. Opioid addiction in pain patients is a major problem experienced in the outpatient clinic from which this study is run, no research has yet been completed on the long-term problems and link to clinical outcomes in patients who are prescribed novel opioid medication for chronic back pain.

In Denmark, a large number of different national registers of health data are available. The data from SpineData, the Danish National Patient Register, and The Danish National Prescription Registry will be used to assess different long-term effects of opioid use on a patient's physical, psychological, and social health. The study will also investigate trends in how opioids are prescribed, how many patients are opioids for a short period when a short term episode of pain occurs, how many patients are being prescribed Long-Term Opioid Therapy (LTOT) for their chronic pain.

Who can participate?
Adult patients with a new spinal pain which lasted for more than 2 months, who attended their first outpatient visit at the participating centre between 2012 and 2013.

What does the study involve?
The participants received an electronic questionnaire three times - at their first visit in the Spinecenter, after 1 year and after 5 years. All participants will have received standard treatment based on their individual needs. No other changes beyond standard care are part of this study.

What are the possible benefits and risks of participating?
The only changes beyond standard care in this study are the completion of three electronic questionnaires, so there is not thought to be an added risk or benefit to participants.

Where is the study run from?
The Spinecenter of Southern Denmark (Denmark)

When is the study starting and how long is it expected to run for?
From January 2018 to June 2021

Who is funding the study?
The Danish Victim Fund, Offerfonden (Denmark)

Who is the main contact?
Prof Claus Manniche
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Danish Data Protection Agency 2008-58-0035

Study information

Scientific Title
Long-Term Opioid Therapy in Spine Center Outpatients: The Spinal Pain Opioid Cohort (SPOC)

Acronym
SPOC

Study objectives

To collate relevant individual patient data over a decade in order to illuminate both the overall group data developments as well as developments relating to individual usage of different opioids during this period and to correlate these findings with the individual patient's physical, psychological, and social data over a 10-year period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/09/2017, the Scientific Ethics Committee of the Region of Southern Denmark (Regionshuset, Damhaven 12, 7100 Vejle, Denmark; +45 7663 8221; komite@regionsyddanmark.dk), ref: S-200112000-29

Primary study design
Observational

Study design
Observational longitudinal study using prospective clinical registry data

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Chronic back pain and long term opioid treatment

Interventions
Clinical data will be collected from patients with a new spinal pain episode lasting for more than 2 months, aged between 18 and 65 years, who had their first outpatient visit to the outpatient Spine Centre setting during 2012-2013. The data will be collected from data in SpineData, the Danish National Patient Register, and The Danish National Prescription Registry between 2012 and 2021. Participants will have been asked to complete follow-up questionnaires in SpineData at the time of their first outpatient Spine Centre visit, and again at 1 and 5 years.

Intervention Type
Other

Primary outcome(s)
Prevalence of patients receiving Long-Term Opioid Therapy (LTOT), defined as receiving six or more opioid prescriptions in a single one-year interval, calculated using clinical data in SpineData, the Danish National Patient Register, and The Danish National Prescription Registry for yearly intervals between 2012 and 2021

Key secondary outcome(s)
Prevalence of patients receiving at least one opioid prescription in a single one-year interval, calculated using clinical data in SpineData, the Danish National Patient Register, and The Danish National Prescription Registry for yearly intervals between 2012 and 2021

Completion date
30/06/2021

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years
2. Experiencing a new pain episode for more than 2 months
3. Presenting at their first outpatient visit at The Spine Centre between 01/11/2012 and 31/12/2013
4. No indications for acute spinal surgery intervention
5. Baseline questionnaires completed with no missing data related to pain intensity

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Basis questionnaires not filled out in SpineData
2. Experiencing symptoms, which indicate serious systemic diseases such as cancer, infections, or inflammatory spondylopathies

Date of first enrolment
01/01/2018

Date of final enrolment
30/06/2021

Locations

Countries of recruitment
Denmark

Study participating centre
Spinecenter of Southern Denmark
Østre Hougvej 55
Middelfart
Denmark
5500

Sponsor information

Organisation
Danish Victim Fund

Funder(s)

Funder type
Government

Funder Name
Offerfonden

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/08/2020	20/07/2020	Yes	No