

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/05/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/07/2020	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Study design

Observational longitudinal study using prospective clinical registry data

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

No participant information sheet available

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 measure

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

Secondary outcome measures

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

Overall study start date

01/01/2018

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

8000

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

Sponsor details

2. sal Toldboden 2

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8800

+45 3392 3334

www.offerfonden@civilstyrelsen.dk

Sponsor type

Government

Website

<http://offerfonden.dk>

Funder(s)

Funder type

Government

Funder Name

Results and Publications

Publication and dissemination plan

Planned publication of 10 papers between 2020 and 2022

Intention to publish date

01/06/2020

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