

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

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<b>Registration date</b> 28/05/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/07/2020	<b>Condition category</b> 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

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**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

## Study design

Observational longitudinal study using prospective clinical registry data

## Primary study design

Observational

## 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?
<a href="#">Protocol article</a>	protocol	19/08/2020	20/07/2020	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes