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Tapering opioids for trauma patients to reduce long-term opioid use

Submission date
26/05/2018

Recruitment status
No longer recruiting

Registration date
17/06/2018

Overall study status
Completed

Last Edited
20/01/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Canadians are the second highest per-person users of opioids in the world. One of the main contributing factors is the increase in opioid prescriptions in the last 20 years. Furthermore, deaths related to opioids have more than doubled since 1990. Long-term use of opioids has been recorded in up to 35% of trauma patients. Education and counseling interventions show promise in decreasing use in post-surgery and long-term pain patients. However, no successfully proven intervention has been designed yet for trauma patients. The Tapering Opioids Prescription Program in Trauma (TOPP-Trauma) was developed to support patients at risk for long-term use of opioids in order to decrease their consumption after hospital discharge.

Who can participate?
Adult trauma patients who are assessed as at risk of long-term opioid use.

What does the study involve?
Patients in the intervention group will have a teaching session while still in hospital. Then after discharge, they will receive six guidance sessions at 2-week intervals on reducing opioid use gradually.

What are the possible benefits and risks of participating?
This study might help to reduce long-term use of opioids and its associated effects, but we cannot guarantee it. The results gathered will help determine if the tools selected and adapted to provide support and guidance in opioid weaning performs as well as for patients who will receive standard of care (pharmacological prescription and educational pamphlet). TOPP-Trauma is not known to be associated with any adverse events. However, such events will be documented if they emerge throughout the study.

Where is the study run from?
Ciusss-du-Nord-de-l'île-de-Montréal (Hôpital Sacré-Coeur de Montréal)

When is the study starting and how long is it expected to run for?
June 2018 to December 2020

Who is funding the study?
Trauma Association of Canada

Who is the main contact?
Melanie Berube, melanie.berube@fsi.ulaval.ca

Study website
N/A

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
N/A

Study information

Scientific Title
Tapering Opioids Prescription Program for Trauma patients at high risk of chronic consumption (TOPP-Trauma): A pilot randomized controlled trial

Acronym
TOPP-Trauma

Study objectives
Although no research hypothesis is generally proposed for a pilot RCT, we believe that patients who will receive TOPP-trauma (experimental group) will consume less opioids than patients who don't receive TOPP-Trauma (control group) at 12 weeks after the beginning of the intervention. Moreover, we hypothesize that more patients in the experimental group will stop consuming opioids at 12 weeks compared with patients in the experimental group. Finally, we expect that the experimental group will have comparable pain intensity and pain interference with activities at 12 weeks in contrast to the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The research proposal was submitted to the CIUSSS du Nord-de-l'Île-de-Montreal ethics board on May 7th, 2018.

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Opioid dependence in trauma patients

Interventions
Two groups will be studied in parallel and followed according to the study time points. In addition to usual care, the control group will receive a pamphlet, while the experimental group will receive a pamphlet and follow TOPP-Trauma.

Participants in the experimental group will receive TOPP-Trauma as well as standard pain management interventions. The biopsychological model of pain, empirical data from previously tested opioid tapering interventions and clinical knowledge on the trauma patient population guided the development of TOPP-Trauma; more specifically components, activities, dosages, and delivery modes. The TOPP-Trauma combines a 20-minute teaching session to be provided the week prior to hospital discharge and a maximum of six 15-minute opioid tapering guidance

sessions given every 2 weeks. An expert trauma nurse or the trauma service pharmacist will provide the teaching and guidance sessions. The teaching session will be based on the information included in the educational pamphlet that will also be distributed to the control group. Guidance sessions will be initiated one week after hospital discharge and will be stopped before the maximum planned sessions if patients cease opioid use. An Intervention Feasibility Evaluation Logbook (Appendix B) will be used to guide expert trauma nurse and the trauma pharmacist to provide the guidance sessions. The treating surgeon will be informed on the participant opioid tapering plan during their appointment at the outpatient clinic to ensure treatment consistency. The number and frequency of guidance sessions was determined based on the established timing for transitioning towards chronic consumption of opioids (i.e. 3 months). Considering that trauma patients admitted in the trauma center where the study will be conducted come from various regions, guidance sessions will be provided individually over the phone or face-to-face at the outpatient clinic at the time of follow-up appointment with the treating surgeon.

The randomization sequence will be generated by a coordinating center to keep researchers blinded. A computerized random-number generator will produce the sequence. Randomization will be undertaken in permuted blocks of 4 to decrease allocation predictability. Tickets will be placed in sealed, opaque, sequentially numbered envelopes to randomize study participants to either the control or experimental group. Participants will be randomized after obtaining baseline data.

Intervention Type
Behavioural

Primary outcome measure
Morphine equivalent dose (MED) per day at 12 weeks after the beginning of TOPP-Trauma.

Secondary outcome measures
1. MED per day at 6 weeks after the beginning of TOPP-Trauma, since some study findings indicated that a great proportion of trauma do not use opioids beyond this period of time
2. Pain intensity and pain interference with activities assessed using the Brief Pain Inventory at baseline and 6 and 12 weeks after the start of the intervention

Overall study start date
01/03/2018

Completion date
01/12/2020

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Able to read and speak French or English
3. ≥2 doses/day of opioids during the 3 previous days
4. At least one risk factor for chronic consumption. The risks factors for chronic consumption are:
4.1. Annual income ≤$40,000
4.2. Injury Severity Score (ISS) ≥12
4.3. Pre-injury use of opioids or substance abuse (Alcohol, Smoking and Substance Involvement Screening Test–version 3.0 ≥11 for alcohol and ≥4 for other substance)

4.4. Anxiety or depression symptoms (scores ≥11 on the Hospital Anxiety and Depression Scale)
4.5. Pain catastrophizing score ≥20 on the Pain Catastrophizing Scale
4.6. Pain self-efficacy score <17 on the Pain Self-Efficacy Questionnaire
5. Discharged directly from hospital to home

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
50

Key exclusion criteria
Cognitive impairment (i.e. moderate-severe traumatic brain injury (TBI) – Glasgow Coma Scale score <13/15, dementia and severe psychiatric disorder) affecting the capacity to participate in the study. In some equivocal situations, where the cognitive function improved during hospitalization, the neurospychologist will provide an evaluation stipulating that patients with moderate TBI can participate in this study.

Date of first enrolment
15/06/2018

Date of final enrolment
31/08/2020

Locations

Countries of recruitment
Canada

Study participating centre
Ciusss-du-Nord-de-l'île-de-Montréal (Hôpital Sacré-Coeur de Montréal)
5400 Boul Gouin O, Montréal, QC
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Sponsor information

Organisation
Trauma Association of Canada

Sponsor details
Kate Mahon (Executive Director)
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Sponsor type
Other

Website
https://www.traumacanada.org

Funder(s)

Funder type
Not defined

Funder Name
Trauma Association of Canada

Results and Publications

Publication and dissemination plan
The research proposal will be submitted to the Canadian Journal of Surgery in June 2018. The results will be submitted for publication in 2019 or 2020 depending of the feasibility of patient recruitment.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

Added 20/01/2022:
The datasets generated during and/or analysed during the current study are/will be available upon request from Melanie Berube (melanie.berube@fsi.ulaval.ca). Data will be available for 5 years (until January 2027). Analyzed data (but not the datasets) will be made available to researchers conducting systematic reviews if deemed necessary.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/05/2019	22/05/2019	Yes	No
Results article		31/08/2021	19/01/2022	Yes	No