Suboxone (buprenorphine/naloxone) versus methadone opioid rotation in patients with escalated opioid use and chronic pain: a randomized trial.

Published: 07-10-2021
Last updated: 22-08-2024

The primary objective is to compare the effectivity of buprenorphine/naloxone and methadone onself-reported opioid misuse. Secondary objectives include comparing the effects on pain, well-being, functioning, and medication use.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON29667

Source
NTR

Brief title
SUMO

Condition

- Psychiatric disorders NEC

Synonym
Opioid use disorder, Methadone, Buprenorphine/naloxone, Chronic pain

Health condition

(Iatrogenic) opioid use disorder, chronic non-malignant pain.

Research involving

Human

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO)

Intervention

Explanation

Outcome measures

Primary outcome

Effect of suboxone and methadone on self-reported opioid misuse.

Secondary outcome

Effects of suboxone and methadone on; - pain (pain intensity, central sensitization , functional interference due to pain); - well-being (quality of life, depression, anxiety, stress, opioid craving, physical functioning, cognitive functioning, perceived recovery); - drug/medication use (dose of original and substitution opioids, concomitant drug and medication use); - side effects; - treatment retention.

Study description

Background summary

Opioid substitution therapy (OST) is a common and effective form of pharmacotherapy in patients with an opioid use disorder and can be done with either buprenorphine or methadone. While these medications have been compared in patients with dependency on illicit opioids, research in patients with dependency on prescription opioids is scarce. It is currently unclear whether buprenorphine or methadon is most effective option in this population. In an open-label, randomized, two-arm, clinical trial, current opioid medication will be substituted by either of these medications.

Study objective

The primary objective is to compare the effectivity of buprenorphine/naloxone and methadone on
self-reported opioid misuse. Secondary objectives include comparing the effects on pain, well-being, functioning, and medication use.

Study design

Open-label randomized controlled trial comparing rotation to methadone with buprenorphine/naloxone in patients with chronic pain and opioid use disorder. Follow-up is six months.

Intervention

Suboxone (buprenorphine/naloxone) vs. methadone.

Study burden and risks

Opioid substitution therapies with suboxone or methadone significantly increase treatment outcomes compared to treatment without pharmacotherapy. Patients are not exposed to additional risks compared to a substitution therapy outside of a study context, as there is extensive clinical experience with both medications and patients will be closely monitored.

Contacts

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Eligibility criteria

Age

Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

- Age 18 or over.

- Meeting ICD-11 criteria for chronic (non-malignant) pain.
- Using a prescribed opioid with an oral morphine equivalent dose of over 60 mg per day for ≥3 months.
- Have an opioid use disorder according to the DSM-5 criteria.
- Wish to be treated for opioid use disorder.
- Willing to comply to study procedures.
- Be able to give informed consent.

Exclusion criteria

- Pregnant, lactating, or planning to become pregnant during the study period.
- Have already used buprenorphine or methadone in the last 4 weeks as a maintenance therapy.
- Escalated use of another substance that prevents safe participation in the study.
- Have acute psychiatric comorbidity.
- Severe respiratory insufficiency or depression, such as severe chronic obstructive pulmonary disease GOLD 3 or 4.
- Serious medical disease, such as severe liver dysfunction (Child-Pugh B or C), severe renal dysfunction (eGFR (MDRD) ≤29), heart failure, current brain trauma.
- A Q-T interval of ≥450 ms on an electrocardiograph (ECG).
- Hypersensitivity or allergy for buprenorphine, naloxone, methadone or any other substance in the preparations of these medications.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-05-2022

Enrollment:	100
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO Date:	08-04-2021
Application type:	First submission
Review commission:	METC Oost-Nederland p/a Radboudumc, huispost 628, Postbus 9101 6500 HB Nijmegen 024 361 3154 commissiemensgebondenonderzoek@radboudumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 52187
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9781
CCMO	NL77333.091.21
EudraCT	2021-001817-35

Study results