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

Published: 08-06-2021
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This study has been transitioned to CTIS with ID 2024-513924-41-01 check the CTIS register for the current data. The primary objective of this study is to compare effectivity of suboxone and methadone on reducing opioid misuse.Secondary objectives...

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

Summary

ID

NL-OMON52187

Source
ToetsingOnline

Brief title
SUMO

Condition

- Psychiatric disorders NEC

Synonym
dependence on opioids, opioid use disorder

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: NWO (NWA)

Intervention

Keyword: buprenorphine, methadone, opioid use disorder, opioids

Outcome measures

Primary outcome

Scores on the Current Opioid Misuse Measure (COMM) questionnaire after two months, compared between both treatments.

Secondary outcome

The mean scores on the following measures, compared between both treatments from baseline to two and six months after initiation of treatment.

Questionnaires: COMM, VAS-pain, BPI, CSI, VAS-QOL, WHOQOLBREF, DASS, VAS-craving, OCDS, GPE, ORSDS, FFMQ-SF, SCS, TCQ, CFQ.

Tests: quantitative sensory testing, 6-minutes walking test, urine toxicology, MoCA,15WT, SCWT, PASAT.

Other: dose of drug, treatment retention.

We will also ask patients to fill the SOAPP-R, SR-MAD and ORT questionnaires, to validate these questionnaires. A genetic sample will be taken to study whether genetic data can predict treatment outcomes.

Study description

Background summary

Chronic non-cancer pain affects around 20% of the general population. An increasing number of chronic pain patients are treated with opioids. About one

in three patients that regularly take opioids for pain meet the DSM-5 criteria for an opioid use disorder (OUD). An OUD can be treated using an opioid substitution therapy (OST), where a short-acting opioid is substituted by a long acting opioid; buprenorphine/naloxone (suboxone) or methadone. OSTs significantly reduce opioid (mis)use and dependency and have a positive effect on analgesia and quality of life. It is currently unclear whether buprenorphine or methadone is the most effective OST option in pain patients with prescription opioid use. Both medications are already used in regular care. We compare effectivity of both medications.

Study objective

This study has been transitioned to CTIS with ID 2024-513924-41-01 check the CTIS register for the current data.

The primary objective of this study is to compare effectivity of suboxone and methadone on reducing opioid misuse.
Secondary objectives include comparing the effects of these two medications on pain, well-being and medication use.

Study design

This is a prospective, randomized, open-label, clinical trial with two parallel treatment arms.

Intervention

There are 2 interventions, each patient will participate in one intervention;
- Treatment with suboxone (buprenorphine/naloxone).
- Treatment with methadon.

Patients will be randomized from their current opioid treatment to suboxone or methadone and treated according to regular care protocols.

Study burden and risks

- Risk: both medications will be used within their indication. Therefore, there are no additional risks compared to treatment outside of a study context.
- Burden: de study measures will take time and can cause slight discomfort. They consist of the following; 1) 4-5x times filling out a number of questionnaires (taking 15 minutes the first 1-2 times, then 3x 30 minutes. 2) Participation in quantitative sensory testing. Sensory thresholds will be tested using thermic, mechanical (pressure) and electric stimuli. This can cause discomfort and will be done 3x (60 minutes each). 3) Participation in walking test, this can cause discomfort for patients who have limited mobility (3x 10 minutes). 4) Giving urine samples (3x) and a saliva sample (1x). 5)

Participation in cognitive tests (3x 20 min) and a computertask (Pavlovian-to-Instrumental Transfer task, 1x30 min).
- Benefits: none.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age 18 or over.
- Meet ICD-11 criteria for chronic pain.
- Using a prescribed opioid with a morphine equivalent dose of over 60 mg per day for >=3 months.
- Have an opioid use disorder according to the DSM-5.
- Wish to be treated for their 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 phase:	4
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

Medical products/devices used

Product type:	Medicine
Brand name:	Methadone
Generic name:	Methadone
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Suboxone
Generic name:	Buprenorphine/naloxone
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	08-06-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-08-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-03-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-04-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-10-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-01-2023
Application type:	Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29667
Source: NTR
Title:

In other registers

Register	ID
EU-CTR	CTIS2024-513924-41-01
EudraCT	EUCTR2021-001817-35-NL
CCMO	NL77333.091.21
Other	NL9781