Influence of oxycodone on individuals taking an SSRI

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To determine the effect of low-dose oxycodone versus placebo in individuals that either use a selective serotonin reuptake inhibitor (SSRI) such as sertraline, paroxetine, citalopram or escitalopram on ventilation at an extrapolated end-tidal carbon...

Ethical review	Approved WMO
Status	Completed
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON51651

Source
ToetsingOnline

Brief title
The OXiS study

Condition

- Mood disorders and disturbances NEC

Synonym
depression, Respiratory depression

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: antidepressants, oxycodone, SSRI, ventilation

Outcome measures

Primary outcome

To determine the effect of low-dose (10 mg) oxycodone versus placebo in individuals that either use paroxetine, citalopram or escitalopram on ventilation at an extrapolated end-tidal carbon dioxide concentration of 55 mmHg at 1 week (4-10 days) of SSRI treatment.

Secondary outcome

To determine the effect of low dose (10 mg) oxycodone versus placebo in individuals that either use paroxetine, citalopram or escitalopram on ventilation at an extrapolated end-tidal carbon dioxide concentration of 55 mmHg following at 1 month (25-45 days) following initiation of SSRI treatment.

To determine the effect of low-dose oxycodone versus placebo in individuals that use and SSRI on pupil diameter.

Study description

Background summary

In a recent study, in collaboration with the US FDA, we observed that 1-5 days paroxetine treatment in healthy volunteers enhanced oxycodone-induced respiratory depression. It remains unknown whether this is true for patients that use an antidepressant such as paroxetine.

Study objective

To determine the effect of low-dose oxycodone versus placebo in individuals

that either use a selective serotonin reuptake inhibitor (SSRI) such as sertraline, paroxetine, citalopram or escitalopram on ventilation at an extrapolated end-tidal carbon dioxide concentration of 55 mmHg.

Study design

This is a randomized double blind, placebo-controlled, crossover study.

Intervention

Subjects will receive an oral oxycodone 10 mg immediate release tablet or a placebo tablet.
Respiration will be measured by rebreating from aballoon.

Study burden and risks

Apart from mild respiratory depression and pissbly nausea, we expete minimal burden to the subjects.

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

1. Signed the informed consent form (ICF) and able to comply with the study requirements and restrictions listed therein;
2. Male and female subjects, age 18 to 75 years, inclusive;
3. Women of childbearing potential (defined as all women who are not surgically sterile or postmenopausal for at least 1 year prior to informed consent) must have a negative serum pregnancy test prior to enrolment and must agree to use a medically acceptable means of contraception from screening through at least 1 month after the last dose of study drug;
4. Body Mass Index (BMI) 18 to 35 kg/m2, inclusive;
5. Stable as defined by the Investigator, based on a medical evaluation that includes the subject*s medical and surgical history, physical examination, vital signs;
6. Using sertraline, paroxetine, citalopram or escitalopram.

Exclusion criteria

1. Currently meet the criteria for diagnosis of moderate or severe substance use disorder according to the DSM-5 criteria on any substances other than caffeine, or nicotine;
2. Any active medical condition, organ disease or concurrent medication or treatment that may either compromise subject safety or interfere with study endpoints;
3. Consume, on average, >27 units/week of alcohol in men and >20 units/week of alcohol in women (1 unit = 1 glass (250 mL) beer, 125 mL glass of wine or 25 mL of 40% spirit);
4. Currently receiving medication-assisted treatment for the treatment of opioid-use disorder;
5. Require on-going prescription or over-the-counter medications that are clinically relevant CYP P450 3A4 or CYP P450 2C8 inducers or inhibitors (e.g., rifampicin, azole antifungals [e.g., ketoconazole], macrolide antibiotics [e.g., erythromycin]);
6. Significant traumatic injury, major surgery, or open biopsy within the prior 4 weeks of informed consent;
7. History of substance use disorder;
8. History of suicidal ideation within 30 days prior to informed consent or history of a suicide attempt in the 6 months prior to informed consent;

9. Measured systolic blood pressure greater than 160 or less than 95 mmHg or diastolic pressure greater than 95 mmHg at screening;
10. History or presence of allergic response to study medication;
11. Treatment with another investigational drug within 3 months prior to dosing or having participated in more than 4 investigational drug studies within 1 year prior to screening;
12. Site staff or subjects affiliated with, or a family member of, site staff directly involved in the study.
13.Current opioid use
14. Opioid use less than 4 weeks before dosing

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	03-05-2023
Enrollment:	55
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Oxynorm
Generic name:	oxycodon
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	11-07-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-09-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	06-01-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	10-02-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	11-02-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2022-001824-13-NL
CCMO	NL81527.058.22

Study results

Date completed: 10-09-2024

Actual enrolment: 5

Summary results
Trial ended prematurely