Esketamine Oral Thin Film (OTF) administration – a pharmacokinetic pharmacodynamic study in healthy participants

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23379

Source
Nationaal Trial Register

Brief title
ESKOT-trial

Health condition

Healthy volunteers

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: LUMC

Intervention

Outcome measures

Primary outcome

Plasma concentrations of S-ketamine and S-norketamine.

Secondary outcome

To determine safety and tolerability of the esketamine oral thin film.

Study description

Background summary

The N-methyl-D-aspartate receptor antagonist ketamine is a potent anesthetic, analgesic and antidepressant, increasingly used at subanesthetic doses to treat differentforms of pain, as well as depression. Currently the intravenous route is the predominant form of ketamine delivery with inherent need for a successful, sterile venipuncture by skilled healthcare personnel. This prevents the use of ketamine in the out-hospital setting, particularly in case of acute pain treatment (e.g., breakthrough pain). In the current study we will perform a pharmacokinetic-pharmacodynamic study on the efficacy of an esketamine oral thin film (OTF) using a cross-over design.

Study objective

We hypothesize that esketamine in OTF formulation will produce plasma Sketamine and S-norketamine concentrations that are associated with adequate antinociception.

Study design

Screening, visit 1, visit 2.

Intervention

Drug administration of esketamine in OTF formulation.

Contacts

Public
LUMC
Pieter Simons

0610301436
Scientific
LUMC
Pieter Simons

0610301436

Eligibility criteria

Inclusion criteria

- aged 18-45 years,
- body mass index > 19 and < 30 kg/m2,
- able to understand the written informed consent form,
- able to communicate with the staff,
- able and willing to complete the study procedures,
- signed the informed consent form,
- deemed suitable by the investigators.
- nonsmoking for the last 3 months.

Exclusion criteria

- Presence or history of any medical or psychiatric disease (incl. a history of substance abuse, anxiety, or the presence of a painful syndrome);
- Use of any medication in the three months prior to the study (incl. paracetamol or other pain
killers);
- Use of more than 21 alcohol units per week;
- Use of illegal substances, including cannabis, in the 4 weeks prior to the study;
- A positive urinary drug test or a breath alcohol test at screening or on the morning of the experiment;
- Pregnancy, lactating or a positive pregnancy test on the morning of the experiment;
- Participation in another drug trial in the 60 days prior to dosing.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	24-01-2021
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
No plan

Ethics review

Positive opinion

Date:	15-01-2021
Application type:	First submission

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
NTR-new	NL9267
Other	METC LDD : P20.111

Study results

Summary results
N/A