Effects of recreational nitrous oxide use on psychomotor functioning related to driving performance

Published: 21-01-2022
Last updated: 12-10-2024

Primary Objective: To answer the question: How long after the use of a typical recreational dose of nitrous oxide (4 liters, 100%, bolus administration via inhalation) is there a measurable negative impact on psychomotor functioning?Secondary…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56364

Source
ToetsingOnline

Brief title
psychomotor effects of nitrous oxide

Condition

- Other condition

Synonym
acute intoxication, being drugged

Health condition

Acute intoxicatie

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Politieacademie

Intervention

Keyword: detection, driving performance, nitrous oxide, psychomotor functioning

Outcome measures

Primary outcome

- Tracking error in mm during divided attention task (DAT)

- Reaction times after appearance of target stimuli during divided attention task (DAT)

Secondary outcome

- Number of correct answers during digit-symbol substitution test (DSST)

- Time required for completion of trailmaking test (TMT)

- Intensity or applicability of subjective experiences in mm as indicated on different visual analog scales (VAS) and drug effects questionnaire (DEQ)

- N2O concentration in exhaled air in parts per million (ppm)

- Baseline nervousness determined as score on state-trait anxiety inventory, state portion (STAI-S, questionnaire)

- Sleep quality during the previous night as score on Groningen Sleep Quality Scale (GSQS, questionnaire)

- Task-related nervousness and metacognition as score on Dundee Stress State Questionnaire (DSSQ, questionnaire)

- Time to start of computer tasks after cessation of drug administration

- Bispectral index during drug administration and task execution

- trait-impulsivity measured with barrat impulsiviness scale (BIS,

questionnaire)

- feelings of depression, anxiety or stress during the week prior to each

testing session, assessed with depression anxiety and stress scale (DASS,

questionnaire)

Study description

Background summary

Nitrous oxide, better known as laughing gas, is a widely used recreational drug that is also frequently found in traffic. However, it is not known how long after use the effects of nitrous oxide adversely affect driving ability.

Study objective

Primary Objective: To answer the question: How long after the use of a typical recreational dose of nitrous oxide (4 liters, 100%, bolus administration via inhalation) is there a measurable negative impact on psychomotor functioning?

Secondary Objective(s): Answer the following research questions:
- Do successive doses have a cumulative impact on psychomotor functioning?
- Is there a relationship between the measured concentration of N2O, in exhaled air, and psychomotor functioning related to
driving ability?
o If so, at what concentrations is there a noticeable deterioration of psychomotor function, i.e. what is the threshold value?
o If yes, until how long after use are the (relevant) concentrations detectable?
- Based on the measured concentrations in the exhaled air, can it be determined at what moment nitrous oxide was used and/or can the period be defined within which the driver will in all likelihood experience limitations with regard to driving ability due to the use of N2O? In other words: what is the relation between the time of concentration in exhaled air and psychomotor performance.

Study design

double-blind, randomized, placebo-controlled crossover trial

Intervention

Subjects go through three experimental conditions,i.e. placebo, a recreational dose of nitrous oxide (4 liters 100% by inhalation), and a double recreational dose of nitrous oxide.

Study burden and risks

A participation consists of 4 visits, namely one training session (2h) and three test sessions (2,5h each). Prior to the training a medical examination takes place on the basis of a medical questionnaire, a possible review of the patient file of the participant, and telephone contact or video chat. Prior to training and test sessions, a urine sample is requested for a drug test (and pregnancy test for female participants) as well as an alcohol breath analysis. During training and testing sessions, several questionnaires are administered and psychomotor tasks (pen-and-paper and computer) are performed. Placebo (medical air) or nitrous oxide is also administered to the participants during the test sessions by inhalation through a balloon. The intended dosage and method of administration of nitrous oxide can lead to short-term decrease in consciousness, ataxia, and hypoxia. However, these effects are transient and with no known risk of lasting effects to the participant. In addition, admitted participants have previous experience with the intended route of administration and dosage, and therefore effects, of nitrous oxide.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 40 Universiteitssingel 40
Maastricht 6229ER
NL
Scientific
Universiteit Maastricht

Universiteitssingel 40 Universiteitssingel 40
Maastricht 6229ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age 18-64
- being in possession of a valid driver's licence (in the Netherlands)
- Being in good physical and mental health as determined by a medical questionnaire and medical examination by a physician.
- Have experience with the use of nitrous oxide (>=1 moment in the past with at least 1x >=2 consecutive doses).
- Experience with the method of administration (100% N2O bolus via balloon inhalation).
- Be fully vaccinated against sars-cov-2 at least 14 days prior to the first physical encounter.
- Applicants who are not or incompletely vaccinated for sars-cov-2 can enroll if they are willing to wear a face mask typ IIR during each visit (with the exception of during drug administration)

Exclusion criteria

-use of nitrous oxide > 10 different times in the past year and/or have used >10 recreational doses (i.e. >10 balloons filled with 3 - 8 liters, 100% nitrous oxide) per time. These limits describe 80% of recreational users (van Amsterdam et al., 2015). Adherence to these limits avoids the inclusion of excessive users whose psychomotor functioning may be impaired by neuropathy associated with excessive use. - Recent use of sedating, stimulating or dissociating drugs. This is assessed by questioning and possibly requesting patient records from GPs. - Recent use of other common intoxicants determined through a urine test at the start of the training and test days (Surestep* urine drug screen casette for amphetamines, benzodiazepines, cocaine, methamphetamines, morphine, THC). - Recent use of alcohol as determined by a positive breath test. - Excessive use of alcohol (>=21 standard glasses per week for men or >=14 standard glasses per week for women) - Pregnancy (determined by Alere* urine hCG test at start of first day of testing) and/or not using any contraceptives for women of childbearing potential - Latex allergy.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-05-2022
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Airapy
Generic name:	Medical air
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Niontix
Generic name:	Nitrous oxide
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	21-01-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	09-06-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-08-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-03-2023
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-04-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-07-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-10-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2021-003242-20-NL
CCMO	NL78086.068.21