Effects of dronabinol (Marinol®) on actual driving, simulated driving and Standardized Field Sobriety Test

Published: 22-07-2009
Last updated: 04-05-2024

Assess the effect of 2 doses (10 and 20 mg) dronabinol on driving performance compared to placebo in light and heavy cannabis users. The heavy users are used as a model for chronic use of dronabinol.

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

Summary

ID

NL-OMON33023

Source
ToetsingOnline

Brief title
Dronabinol and driving

Condition

- Other condition

Synonym
driving, perception

Health condition

cognitief en motorisch functioneren

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cannabis, Driving, Dronabinol, Pain

Outcome measures

Primary outcome

Standard Deviation of Lateral Position in the driving task.

Secondary outcome

Highway driving and car following on the road and in the simulator.

Field Sobriety Test.

Visual analogue scales of drugeffect.

Addiction Research Center Inventory: Marijuana scale.

THC + metabolites concentration in blood and saliva.

Study description

Background summary

Dronabinol is a new medicine and is used for the treatment of chronic pain, anorexia in AIDS and other wasting diseases and as antiemetic medication in cancer patients receiving chemotherapy. The active ingredient is synthetic THC (cannabis) which also occurs naturally in the cannabis sativa plant. It is known that cannabis reduces driving performance especially in less experienced users. Since dronabinol is administered orally, it has a different pharmacokinetic profile and it might also have a different pharmacodynamic effect. Because road safety might be compromised when people drive under the influence of a drug that influences driving performance and because this has not been investigated yet, this study will be relevant to the general society.

Study objective

Assess the effect of 2 doses (10 and 20 mg) dronabinol on driving performance compared to placebo in light and heavy cannabis users. The heavy users are used as a model for chronic use of dronabinol.

Study design

The design is double-blind, placebo-controlled, 3-way crossover.

Intervention

All subjects will participate in the following conditions:
1. Dronabinol 10 mg
2. Dronabinol 20 mg
3. Placebo

Study burden and risks

Volunteers visit the University and will be guided by a researcher for physical examination (45 minutes), a training (2.5 hours) and 3 testsessions (6 hours per session). Total will be 21.25 hours over 4 weeks.
5 ml of blood will be drawn at the physical examination (1x) and during the test sessions (4x per session). The participants will perform driving tasks, the field sobriety tests and fill out questionnaires during the test sessions. Side effects of dronabinol that might occur at the used dose are dizziness, confusion, somnolence and feeling high.

Contacts

Public
Universiteit Maastricht

Postbus 616
6200 MD Maastricht
Nederland
Scientific
Universiteit Maastricht

Postbus 616
6200 MD Maastricht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Experience with the use of cannabis
Good physical health and free from psychotropic medication
Body Mass Index between 18 and 28
Valid driving license
Able to give written informed consent
Aged between 18 and 40 years

Exclusion criteria

History of drug abuse or addiction
Pregnancy or lactation
Cardiovascular abnormalities
Excessive drinking (>20 drinks/week)
Hypertension
History of or current psychiatric disorder
Susceptibility to simulator sickness
Allergy to sesame oil

Study design

Design

Study phase:	4
Study type:	Interventional

Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-12-2009
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Marinol
Generic name:	dronabinol

Ethics review

Approved WMO

Date:	22-07-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	21-09-2009
Application type:	First submission
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	EUCTR2009-014402-33-NL
CCMO	NL28992.068.09