A double-blind, randomized, placebo controlled, partial 4-way crossover interaction study to examine the effects of a single dose of haloperidol or placebo on THC-induced CNS effects in healthy male volunteers

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The current study is designed as a first exploration of this model. The hypothesis is that haloperidol will lead to an amelioration of the *psychotomimetic* effects of the THC-challenge.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32373

Source
ToetsingOnline

Brief title
Study to examine the effects of haloperidol on THC in healthy males

Condition

- Other condition

Synonym
denkstoornis), hallucinaties, psychosis (wanen

Health condition

psychosen

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: CHDR (Centre for Human Drug Research)

Intervention

Keyword: gezonde vrijwilligers, haloperidol, psychosis, THC

Outcome measures

Primary outcome

To examine the effects of haloperidol on the CNS-effects of THC compared to

placebo.

Secondary outcome

To examine the CNS-effects of haloperidol

To examine the CNS-effects of THC

Study description

Background summary

As there is a large amount of evidence for the relation between cannabis and psychosis and the possible increase of forebrain dopamine by THC, THC-induced psychotomimetic effects could be used as a practical *psychosis*-model, to assess therapeutic effects of (novel) antipsychotic agents.

Study objective

The current study is designed as a first exploration of this model. The hypothesis is that haloperidol will lead to an amelioration of the *psychotomimetic* effects of the THC-challenge.

Study design

This will be a double-blind, randomized, placebo controlled, partial 4-way crossover interaction study in healthy volunteers.

Intervention

The two drugs used in the study are haloperidol 3 mg orally administrated and THC intrapulmonary (2, 4, 6 mg with intervals of 90 minutes) or the placebos of both drugs.

Study burden and risks

Side-effects haloperidol:
- expected: sleepiness, lightheadedness (upon standing), dizziness: these effects usually disappear within a couple of hours.
- rare: dystonia: for this rare side-effect there will be biperideen (Akineton®). The effect of biperideen occurs rapidly, usually within 20 minutes.
Side-effects THC: some people experience the relaxing effects of THC and feel free of troubles, whereas other people feel terrified or confused. THC is an appetizer and causes muscle relaxation. Short memory is impaired and an increase in heart rate is observed. Given the short period of use these side effects are expected to be mild and expected to last for only a couple of hours after the last inhalation. People who are sensitive to the effects of marijuana can develop a psychosis in the short term. That*s why people with a history of psychosis cannot participate in this study.

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

See protocol paragraph 3.2

Exclusion criteria

See protocol paragraph 3.3

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2007

Enrollment:	24
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	haldol
Generic name:	haloperidol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	tetrahydrocannabinol
Generic name:	tetrahydrocannabinol

Ethics review

Approved WMO Date:	03-10-2007
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	16-11-2007
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	09-01-2008
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	24-07-2008
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	07-10-2009
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	EUCTR2007-000140-27-NL
CCMO	NL19815.058.07