

The effect of Marinol (tetra-9-hydrocannabinol) on the frequency of TLESRs.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21968

Source

NTR

Brief title

N/A

Intervention

Outcome measures

Primary outcome

Frequency of transient lower esophageal sfincter relaxations (TLESRs) measured by esophageal manometry up to 3hours postprandially.

Secondary outcome

Rate of acid reflux episodes measured with pH-metry for 3 hours postprandially, basal lower esophageal sphincter pressure (LESp) measured by manometry.

Study description

Background summary

Remark randomization: Every subject is his own control.

Study objective

Cannabinoid receptor (CB1) agonists, like marinol, lower the rate of TLESRs and can be useful in the treatment of gastroesophageal reflux disease (GERD).

Study design

N/A

Intervention

Twice a 4 hours esophageal manometry and pH-metry (transnasally).

Single dose of 10mg marinol (delta-9-hydrocannabinol, THC) and a single dose of placebo.

Contacts

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Eligibility criteria

Inclusion criteria

1. Man,
2. 18-55 years,
3. 65-100kg,
4. bmi 19-30 kg/m²,
5. normal physical and laboratory findings at start of study.

Exclusion criteria

1. Clinical relevant illness two weeks prior to start of study;
2. systemic illness which influence esophageal motility;
3. use of drugs that influence gastrointestinal motility;
4. drug abuse,
5. mania, depression, schizophrenia or another mental illness;
6. cardiac complaints as hypo-. hypertension, syncope, tachycardia;
7. cannabis allergy,
8. sesame oil allergy or another severe allergy.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control: Placebo

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 03-05-2004
Enrollment: 18
Type: Actual

Ethics review

Positive opinion
Date: 31-05-2005
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	NL30
NTR-old	NTR52
Other	: MEC 04/084
ISRCTN	ISRCTN34437109

Study results

Summary results

N/A