

The effect of Marinol (tetra-9-hydrocannabinol) on the frequency of transient lower oesophageal sphincter relaxations (TLESRs)

Submission date 04/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/08/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/06/2008	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR52

Study information

Scientific Title

Study objectives

Cannabinoid receptor (CB1) agonists, like marinol, lower the rate of transient lower oesophageal sphincter relaxations (TLESRs) and can be useful in the treatment of gastro-oesophageal reflux disease (GERD).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local ethics committee.

Study design

Double-blind, placebo-controlled, crossover, randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Gastro-oesophageal reflux disease (GERD)

Interventions

Twice a four-hour oesophageal manometry and pH-metry (transnasally). Single dose of 10 mg marinol (tetra-9-hydrocannabinol [THC]) and a single dose of placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Marinol

Primary outcome measure

Frequency of TLESRs measured by oesophageal manometry up to three hours post-prandially.

Secondary outcome measures

Rate of acid reflux episodes measured with pH-metry for three hours post-prandially, basal lower oesophageal sphincter pressure (LESp) measured by manometry.

Overall study start date

03/05/2004

Completion date

01/06/2005

Eligibility

Key inclusion criteria

1. Male
2. Aged 18 - 55 years
3. 65 - 100 kg, body mass index (BMI) 19 - 30 kg/m²
4. Normal physical and laboratorial findings at start of study

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

55 Years

Sex

Male

Target number of participants

18

Key exclusion criteria

1. Clinical relevant illness two weeks prior to start of study
2. Systemic illness which influence oesophageal motility
3. Use of drugs that influence gastrointestinal motility
4. Drug abuse, mania, depression, schizophrenia or another mental illness
5. Cardiac complaints such as hypotension, hypertension, syncope, tachycardia
6. Cannabis allergy, sesame oil allergy or another severe allergy

Date of first enrolment

03/05/2004

Date of final enrolment

01/06/2005

Locations

Countries of recruitment

Netherlands

Study participating centre

Meibergdreef 9

Amsterdam

Netherlands

1105 AZ

Sponsor information

Organisation

Academic Medical Centre (AMC) (The Netherlands)

Sponsor details

Emma Kinderziekenhuis

Postbus 22660

Amsterdam

Netherlands

1105 AZ

Sponsor type

University/education

Website

<http://www.amc.uva.nl/>

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Industry

Funder Name

AstraZeneca R&D Mölndal (Sweden)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration