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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/08/2005	**Overall study status** Completed	
Last Edited 10/06/2008	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr G.E.E. Boeckxstaens

Contact details
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ
+31 (0)20 566 7375
g.e.boeckxstaens@amc.uva.nl

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/m^2
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, schizofrenia 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