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The dopaminergic system in patients with functional dyspepsia analyzed by an alpha-methyl-para-tyrosine (AMPT) challenge test and single photon emission computed tomography (SPECT) imaging before and after treatment with amitriptyline

Submission date 07/06/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/06/2006	**Overall study status** Completed	
Last Edited 07/09/2011	**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
Academic Medical Center (AMC)
Department of Gastroenterology
C2-328
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 5667375
g.e.boeckxstaens@amc.uva.nl

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Study objectives
Patients (stress-sensitive) with functional dyspepsia have a change in their dopaminergic system, through chronic stress, which leads to visceral hypersensitivity and therefore dyspeptic symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Non-randomized, placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Functional dyspepsia (FD)

Interventions
1. Amitriptyline or placebo for the patient group (see the amitriptyline study)
2. Single photon emission computed tomography (SPECT) imaging with radioligand (123I) iodobenzamide ([123I]IBZM)
3. Alpha-methyl-paratyrosine (AMPT/metyrosine) challenge test; 2 x 500 mg

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Amitriptyline

Primary outcome(s)
To evaluate if patients with functional dyspepsia have a change in their dopaminergic system that leads to visceral hypersensitivity

Key secondary outcome(s))
Has amitriptyline a positive effect on those changes in the dopaminergic system through reducing the stress?

Completion date
01/05/2009

Eligibility

Key inclusion criteria
1. Age 18-65 years
2. Functional dyspepsia (Nepean dyspepsia index [NDI] >25)
3. Take part in the amitriptyline study (ISRCTN76116512)
4. No effect on proton pump inhibitor (PPI), or a constant three-month dosage of PPI
5. No depression (Zung self-rating depression scale <50)
6. No medications which influence the intestine

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Gastroduodenal surgery
2. Reflux-like dyspepsia (Rome II criteria)
3. Use of antidepressants
4. Organic abnormalities
5. Pregnancy
6. Severe cardiac, renal, pulmonary, hepatic or systemic diseases, hyperthyroidism, glaucoma and epilepsy
7. Metal implants

Date of first enrolment
01/05/2006

Date of final enrolment
01/05/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Center (AMC), Department of Gastroenterology (The Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
University/education

Funder Name
Academic Medical Center (AMC)

Alternative Name(s)
Academic Medical Center, AMC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration