ISRCTN04559282 https://doi.org/10.1186/ISRCTN04559282

Influence of the polymorphism of the serotonin transporter promoter gene on effects of selective serotonin re-uptake inhibitors (SSRIs) in experimental panic provocation

Submission date
22/08/2005

Recruitment status
No longer recruiting

Registration date
16/09/2005

Overall study status
Completed

Last Edited
06/07/2010

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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
KE 595/7

Study information

Scientific Title

Acronym
KE 595/7

Study objectives
SSRIs influence psychometric, neuropsychological, autonomous, psychophysiological and neuroendocrine parameters at basal conditions and during CCK-4 stimulation in healthy volunteers.
There are differences according to the genotype for the promoter for the serotonin transporter.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
International

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Mental and behavioural disorders

Interventions
Treatment with SSRI versus placebo for eight weeks (double-blind, randomized, within-subjects cross-over), CCK-4 challenge on respective days 42

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
PANAS under basal conditions and IDCL for panic items and 100 mm VAS for 'anxiety' and 'tension' after CCK-4 challenge

Secondary outcome measures
Other psychometric, neuropsychological, autonomous, psychophysiological and neuroendocrine parameters

Overall study start date
01/09/2005

Completion date
01/09/2006

Eligibility

Key inclusion criteria
Healthy volunteers (age 18-40 years)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Not Specified

Target number of participants
30

Key exclusion criteria
1. Current and life-time psychiatric disorders
2. Medical or neurological illnesses
3. Shift work
4. Transcontinental flights during the past four weeks

Date of first enrolment

01/09/2005

Date of final enrolment
01/09/2006

Locations

Countries of recruitment
Germany

Study participating centre
c/o University Hospital Hamburg
Hamburg
Germany
20246

Sponsor information

Organisation
Individual Sponsor (Germany)

Sponsor details
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Sponsor type
University/education

Funder(s)

Funder type
Research council

Funder Name
Deutsche Forschungsgemeinschaft (DFG)

Alternative Name(s)
German Research Association, German Research Foundation, DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Funder Name
For psychophysiological and autonomous parameters only: Lundbeck

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/05/2010		Yes	No