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

Contact name
Dr Michael Kellner

Contact details
c/o University Hospital Hamburg
Dept of Psychiatry
Martinistrasse 52
Hamburg
Germany
20246
+49 40 428032234
kellner@uke.uni-hamburg.de

Additional identifiers

Protocol serial number
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

Study type(s)

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(s)
PANAS under basal conditions and IDCL for panic items and 100 mm VAS for 'anxiety' and 'tension' after CCK-4 challenge

Key secondary outcome(s))
Other psychometric, neuropsychological, autonomous, psychophysiological and neuroendocrine parameters

Completion date
01/09/2006

Eligibility

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

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
40 years

Sex

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)

Funder(s)

Funder type
Research council

Funder Name
Deutsche Forschungsgemeinschaft (DFG)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

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