

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	☐ Prospectively registered
Registration date 16/09/2005	Overall study status Completed	☐ Protocol
Last Edited 06/07/2010	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ 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

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

Primary study design

Interventional

Study design

Randomised controlled trial

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