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

Recruitment status No longer recruiting	Prospectively registered		
	∐ Protocol		
Overall study status Completed	Statistical analysis plan		
	[X] Results		
Condition category Mental and Behavioural Disorders	Individual participant data		
	No longer recruiting Overall study status Completed		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 recruitmentGermany

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

Sponsor information

Organisation

Individual Sponsor (Germany)

Sponsor details

Michael Kellner c/o University Hospital Hamburg Dept. of Psychiatry Martinistrasse 52 Hamburg Germany 20246 +49 (0)40 428032234 kellner@uke.uni-hamburg.de

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