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Tryptophan depletion in patients with Selective Serotonin Reuptake Inhibitor (SSRI)-remitted anxiety disorders

Submission date
15/04/2005

Recruitment status
No longer recruiting

Registration date
10/05/2005

Overall study status
Completed

Last Edited
12/01/2021

Condition category
Mental and Behavioural Disorders

[X] 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

Protocol serial number
RA/4/1/1193, ACTRN12609000170224

Study information

Scientific Title

Tryptophan depletion in patients with Selective Serotonin Reuptake Inhibitor (SSRI)-remitted anxiety disorders

Study objectives
Primary hypotheses:
1. Tryptophan depletion (TD) will cause transient symptom relapse in SSRI-remitted GAD patients, but only when challenged with the 7.5% CO2 provocation paradigm (Study 2)
2. OCD patients well on SSRIs will not relapse spontaneously when undergoing TD but will suffer a significant worsening of anxiety when exposed to a personalised phobic stimulus (Study 1)

Secondary hypotheses:
1. TD will have a greater impact upon women than men, according to primary outcome measures
2. Women will experience more nausea on the occasion that they have the tryptophan-restored (control) drink than on the tryptophan-depleted occasion
3. Transient depressive symptoms will be seen in subjects with a past history of depressive illness, despite the absence of a current or recent diagnosis of a depressive disorder

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)
Not Specified

Health condition(s) or problem(s) studied
Obsessive-compulsive disorder (OCD); Generalised anxiety disorder (GAD).

Interventions
1. Tryptophan depletion (double-blind crossover) vs tryptophan restored intervention

2. Disorder specific provocation, viz:
a. 20 min 7.5% CO2 inhalation or air (GAD)
b. Exposure to a known anxiogenic stimulus (OCD)

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Study 1: Visual Analogue Scales (VAS), The Spielberger State Anxiety Inventory (STAI), tryptophan levels, c. Profile of Mood States (POMS), Yale-Brown Obsessive Compulsive Scale (Y-

BOCS)
Study 2: Visual Analogue Scales (VAS), The Spielberger State Anxiety Inventory (STAI), tryptophan levels, c. Profile of Mood States(POMS), Generalised Anxiety Disorder Inventory (GADI)

Key secondary outcome(s))
Beck Depression Inventory (BDI), Blood pressure/heart rate data, Swedish universities Scales of Personality (SSP).

Completion date
31/12/2006

Eligibility

Key inclusion criteria
Study 1: Primary diagnosis of obsessive-compulsive disorder (OCD), currently remitted with SSRI therapy
Study 2: Primary diagnosis of generalised anxiety disorder (GAD), currently remitted with SSRI therapy
Aged 18-65
Able and willing to give informed consent prior to participation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
12

Key exclusion criteria
1. No significant co-morbid anxiety disorder or other psychiatric disorder including alcohol or drug dependence
2. No major depressive episode with past 6 months
3. No significant other illness
4. No significant other medication therapy
5. No psychological therapy applied this episode

Date of first enrolment
01/07/2005

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Australia

Study participating centre
School of Psychiatry and Clinical Neurosciences (M521)
Perth
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6009

Sponsor information

Organisation
Raine Medical Research Foundation (Australia)

ROR
https://ror.org/04agdqh30

Funder(s)

Funder type
Research organisation

Funder Name
Raine Priming Grant 2005-6.

Results and Publications

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	01/02/2010	12/01/2021	Yes	No