

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

Submission date 15/04/2005	Recruitment status No longer recruiting	☒ Prospectively registered
Registration date 10/05/2005	Overall study status Completed	☐ Protocol
Last Edited 12/01/2021	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

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

Primary study design

Interventional

Study design

Randomised controlled trial

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

Australia

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