ISRCTN01523262 https://doi.org/10.1186/ISRCTN01523262

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

| Submission date | Recruitment status |
|---|---|
| 15/04/2005 | No longer recruiting |
| **Registration date** | **Overall study status** |
| 10/05/2005 | Completed |
| **Last Edited** | **Condition category** |
| 12/01/2021 | 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Not Specified

### Participant information sheet

### 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 measure
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)

### Secondary outcome measures
Beck Depression Inventory (BDI), Blood pressure/heart rate data, Swedish universities Scales of Personality (SSP).

### Overall study start date
01/07/2005

### 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

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
65 Years

### Sex
Both

### Target number of participants
28

### 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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## Sponsor information

### Organisation
Raine Medical Research Foundation (Australia)

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### Sponsor type
Research organisation

### ROR
https://ror.org/04agdqh30

## Funder(s)

### Funder type
Research organisation

### Funder Name
Raine Priming Grant 2005-6.

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