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Serotonin regulation of the human stress response

Submission date	Recruitment status	[ ] Prospectively registered
15/04/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/05/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/09/2011	Mental and Behavioural Disorders	

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/4/1/1109

Study information

Scientific Title

Study objectives
1. Tryptophan depletion will increase the anxiogenic response to single breath 35% CO2 in normal volunteers, as compared with an air inhalation.
2. Single breath 35% CO2 inhalation in normal volunteers will induce cortisol and prolactin release.
3. Tryptophan depletion will significantly increase the magnitude of single breath 35% CO2 induced cortisol and prolactin release in normal volunteers.
4. Tryptophan depletion will exacerbate single breath 35% CO2 inhalation induced hypertension and bradycardia in normal volunteers.

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
Stress/Anxiety

Interventions
1. Tryptophan depletion, double-blind crossover with Tryptophan restored intervention
2. Single breath 35% CO2 inhalation single blind crossover with single breath room air

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Visual Analogue rating Scales (VAS), The Spielberger State Anxiety Inventory (STAI), Cortisol & tryptophan levels.

Secondary outcome measures
The Panic Symptom Inventory (PSI), Prolactin levels, Blood pressure/heart rate data, Swedish universities Scales of Personality (SSP)

Overall study start date
01/04/2005

Completion date
31/07/2005

Eligibility

Key inclusion criteria
1. Healthy volunteers aged 18-65
2. Able & willing to give informed consent prior to participation

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
14

Key exclusion criteria
Any psychiatric morbidity by GP report, psychiatric clinical interview, or MINI v5 (Sheehan et al. 1998) semi-structured interview

Date of first enrolment
01/04/2005

Date of final enrolment
31/07/2005

Locations

Countries of recruitment
Australia

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

Sponsor information

Organisation
University of Western Australia (Australia)

Sponsor details
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Sponsor type
University/education

Website
http://www.uwa.edu.au/

ROR
https://ror.org/047272k79

Funder(s)

Funder type
University/education

Funder Name
University of Western Australia Research Grants Scheme 2004 (Australia) (ref: RA/1/485/)

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	01/10/2006		Yes	No