ISRCTN76669810 https://doi.org/10.1186/ISRCTN76669810

Further development of a new model of generalised anxiety disorder: effects on processing of emotional material

Submission date	Recruitment status	[ ] Prospectively registered
28/09/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/07/2017	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Marcus Munafo

Contact details
C/O Research and Effectiveness Department
Level 1, Old Building
Bristol Royal Infirmary
Marborough Street
Bristol
United Kingdom
BS2 8HW
+44 (0)117 928 3473
R&E@ubht.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0264192826

Study information

Scientific Title
Further development of a new model of generalised anxiety disorder: effects on processing of emotional material

Study objectives
This study will enable us to learn more about how the inhalation of carbon dioxide (CO2) produces anxiety. We can examine the psychological mechanisms of CO2-induced anxiety and see how these influence the processing of emotional material. These findings will aid our understanding of anxiety and validate the CO2 model for use in studies of potential new treatments. It is widely accepted that anxiety results in altered processing of emotional material. Anxiety is also associated with physical symptoms such as racing heart, raised blood pressure, and muscle tension. We aim to examine the relationship between heart rate and blood pressure and altered processing of emotional material (i.e., are changes in the physical response to CO2 related to changes in the psychological response?).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Double-blind placebo-controlled randomised crossover study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
General anxiety disorder

Interventions

Participants will complete a single test session, which will consist of the inhalation of air and the inhalation of 7.5% CO2, in counterbalanced order.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Measures of processing of emotional information

Secondary outcome measures
Subjective measures of anxiety and cardiovascular function

Overall study start date
01/01/2007

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Male and female participants
2. Aged 18-55
3. With a normal medical and psychiatric history, physical examination and ECG who give signed, fully-informed consent to participate

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
20

Key exclusion criteria

1. Females who are pregnant, breastfeeding, or not using adequate contraception
2. Presence of any pathological condition
3. Personal history of current or past psychiatric illness by psychiatric interview
4. Strong family history of mood disorder, including panic disorder
5. Personal history of cardiovascular or respiratory disease, including asthma
6. Personal history of migraine headaches requiring treatment
7. Cigarette smoking in the last 6 months
8. Drinking more than the recommended units of alcohol per week
9. Personal history of alcoholism or drug dependence
10. Drinking more than 8 caffeinated drinks per day
11. Medication use (except local treatment, or aspirin or paracetamol) within 8 weeks of testing
12. Potential, in the opinion of the investigator, to be non-compliant with study

Date of first enrolment
01/01/2007

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Royal Infirmary
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom

SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
United Bristol Healthcare NHS Trust

Funder Name
NHS R&D Support Funding

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