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American skullcap (Scutellaria lateriflora): a study of its effects on mood in healthy volunteers

Submission date	Recruitment status	[X] Prospectively registered
01/07/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/09/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/06/2014	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
UW080921

Study information

Scientific Title
An investigation of the psychological, somatic and related social effects resulting from the use of American skullcap (Scutellaria lateriflora): a randomised placebo-controlled crossover study in healthy volunteers

Study objectives
Anxiety is a common but potentially serious disorder as it can lead to both somatic and social dysfunction. Orthodox anxiolytics are associated with unpleasant side-effects and dependency. There is therefore an urgent need for safe, well-tolerated and effective alternatives. American skullcap (Scutellaria lateriflora) is a popular herb in traditional medicine systems and the western herbal medicine Materia medica is used for anxiety, stress, hysteria, tremors, sleep disorders, panic, tension, and related disorders. It is reported to have minimal side-effects and no known toxicity. It is therefore an ideal candidate for providing evidence for its efficacy and safety with a view to its widespread use as a licensed product, for the reduction of anxiety, stress and related co-morbidities.

Research question:
Can Scutellaria lateriflora extracts provide an effective treatment for reducing anxiety and stress?

Study hypotheses:
1. S. lateriflora will have a superior anxiolytic effect to placebo
2. The safety profile of S. lateriflora will be comparable to that of placebo
3. S. lateriflora will reduce anxiety without a marked diminution of cognition or energy
4. S. lateriflora will decrease salivary cortisol levels in moderately anxious individuals

On 07/09/2009 this record was updated to include a new anticipated start date; the initial start date at the time of registration was 01/09/2009.

On 24/03/2011 this record was updated to include an edited public title, scientific title, inclusion criteria, exclusion criteria, anticipated start and end dates and status of trial.

Previous public title:
American skullcap (Scutellaria lateriflora) for anxiety and stress: an efficacy study in healthy volunteers

Previous scientific title:
An investigation of the psychological, somatic and related social effects resulting from the use of American skullcap (Scutellaria lateriflora) in the treatment of anxiety and stress: a randomised placebo-controlled crossover study in healthy volunteers with self-reported moderate anxiety

The previous start date was 01/11/2009 and the previous end date was 01/12/2010.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Westminster Research Ethics Sub-Committee, 24/4/2009, ref: 08/09/21

Study design
Interventional randomised double-blind (subjects, investigators/outcome assessors) placebo-controlled crossover study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Moderate anxiety

Interventions
Intervention: organic freeze-dried Scutellaria lateriflora capsules 350 mg three times daily
Placebo control: organic freeze-dried stinging nettle leaf (Urtica dioica folia) capsules 300 mg three times daily

The study will last for 38 days including a 7-day washout period. Participants will be randomly assigned to receive either freeze-dried Scutellaria lateriflora test or freeze-dried Urtica dioica folia placebo three times daily for half of the intervention study duration and then, following a washout period of 1 week, will cross over to receive the other for comparison. In other words, participants will be acting as their own controls.

Clinical reporting scales and salivary cortisol measurements will be used to compare anxiety symptoms and quality of life at the beginning, before the end of the first half prior to crossover, and at the end of the clinical study. There have been no reports of toxicity associated with S. lateriflora. To confirm its safety profile, all participants will undergo fingerpick blood extraction for liver function analysis pre-, intermediate and post-intervention.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Scutellaria lateriflora, Urtica dioica folia

Primary outcome measure

Reduction in anxiety following 2 weeks' intervention in comparison to placebo control, indicated by a significantly reduced score on the Beck Anxiety Inventory, projected to be at least 10 points (0 - 7 = no anxiety-minimal anxiety; 8 - 15 = mild anxiety; 16 - 25 = moderate anxiety; 26 - 63 = severe anxiety).

Secondary outcome measures
1. Self-reported changes in quality of life
2. Changes in salivary cortisol measurements to indicate a reduction in stress levels
3. Live blood analysis of liver function by fingerprick blood extraction

Sampling and testing for secondary outcome measures will be conducted prior to commencement of the interventional stage of the study in order to take baseline measurements for comparison with subsequent measurements, during the last 2 days of the first half of the intervention prior to a 7-day washout period and during the last 2 days of the second half of the intervention study following crossover. Pulse and blood pressure will also be assessed at these time-points as a matter of interest.

Overall study start date
01/04/2011

Completion date
30/10/2011

Eligibility

Key inclusion criteria
Current inclusion criteria as of 24/03/2011:
1. Aged 18 - 75 years, either sex
2. Good general health
3. Males and females
4. Participants will be volunteers and will have given informed consent
5. Agree to undergo a fingerprick blood test for analysis of liver function pre-, intermediate- and post-intervention

Previous inclusion criteria:
1. Symptoms of moderate anxiety, indicated by a cut-off score point for anxiety on the Beck Anxiety Inventory (BAI) between 16 - 25
2. Aged 18 - 75 years, either sex
3. Good general health
4. Males and females
5. Participants will be volunteers and will have given informed consent
6. Agree to undergo a fingerprick blood test for analysis of liver function pre-, intermediate- and post-intervention

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
42

Key exclusion criteria
Current exclusion criteria as of 24/03/2011:
1. Alcohol, tobacco or recreational drug dependence
2. Known hypersensitivity to any herbal medicines when taken orally
3. Current use or use within the past month of antipsychotic medication, e.g., tranquilisers, antidepressants, or sedatives
4. A history of (diagnosed) severe psychiatric disorders, e.g., clinical depression, bipolar disorder or generalised anxiety disorder
5. Neurological, immunological or endocrinological disorders
6. Liver disease, kidney disease, cancer, diabetes mellitus, malignant hypertension or any other serious medical condition
7. Moderate-high depression, i.e., Hospital Anxiety and Depression Scale (HADS) scores 8 - 21
8. Those currently on, or with a recent history of using, synthetic hormones (other than the contraceptive pill), including sprays or topical corticosteroid analogues
9. Those taking herbs or supplements that many have either a direct or indirect effect on the HPA axis (e.g., dopaminergic, serotonergic, gamma-aminobutyric acid [GABA] -ergic)
10. Pregnancy or lactation
11. Those under 18 or over 75
12. Refusal to undergo blood tests

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6. Liver disease, kidney disease, cancer, diabetes mellitus, malignant hypertension or any other serious medical condition
7. Moderate-high depression, i.e., Hospital Anxiety and Depression Scale (HADS) scores 8 - 21
8. Initial scores of above 26 in the BAI, indicating severe anxiety
9. Initial scores below 16 in the BAI, indicating mild anxiety
10. Those currently on, or with a recent history of using, synthetic hormones (other than the contraceptive pill), including sprays or topical corticosteroid analogues
11. Those taking herbs or supplements that many have either a direct or indirect effect on the HPA axis (e.g., dopaminergic, serotonergic, gamma-aminobutyric acid [GABA] -ergic)

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Date of first enrolment
01/04/2011

Date of final enrolment
30/10/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Westminster
London
United Kingdom
W1W 6UW

Sponsor information

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Sponsor type
University/education

Website
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ROR
https://ror.org/04ycpbx82

Funder(s)

Funder type
University/education

Funder Name
University of Westminster (UK) - Institute of Health and Wellbeing

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	01/05/2014		Yes	No