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A 2 x 2 phase II randomised controlled trial to investigate the efficacy of St John's wort versus placebo in smoking cessation and the efficacy of chromium intake in preventing weight gain

Submission date
08/02/2006

Registration date
24/02/2006

Last Edited
18/01/2012

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[ ] 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

BMS2/05

Study information

Scientific Title

Acronym
SJW

Study objectives
Our hypothesis is that St John's wort (SJW) will help people to stop smoking through its effects on dopamine, acetylcholine nicotinic receptors and serotonin to reduce the symptoms that occur following quitting and that chromium will reduce weight gain following quitting through its effects on insulin sensitivity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the local NHS Oxfordshire Ethics Committee

Study design
2 x 2 phase II randomised placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Smoking cessation

Interventions
Patients are randomised to receive one of the following interventions:
1. SJW and chromium
2. Chromium and placebo
3. SJW and placebo
4. Control: placebo and placebo

Intervention Type

Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
St John's wort

Primary outcome measure
For SJW, primary outcome will be quitting at four weeks post quit, the standard for the NHS. For chromium, primary outcome will be weight change as defined by week 4 minus week 0 weight.

Secondary outcome measures
Relating to SJW, secondary outcomes include:
1. Side-effects of SJW withdrawal symptoms
2. Changes in State Trait Anxiety Inventory (STAI)
3. Questionnaire of Smoking Urges (QSU) brief
4. Mood and Physical Symptoms Scale (MPSS) questionnaires
5. Changes in salivary cortisol profile, plasma prolactin and free tryptophan

For chromium, secondary outcomes include:
1. Changes in food frequency questionnaire
2. Metabolic changes that might follow from changes in carbohydrate and lipid metabolism as a result of chromium. These are free tryptophan, Non-Esterified Free Fatty Acids (NEFFAs), Large Neutral Amino Acids (LNAAs), triglycerides and change in body fat estimated through bioimpedance.

Overall study start date
21/02/2006

Completion date
31/08/2006

Eligibility

Key inclusion criteria
Smokers 18 or over that want to stop smoking in the next two weeks and that have smoked at least 10 cigarettes per day for the past year and are clinically suitable to take SJW and chromium.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
144

Key exclusion criteria
1. Pregnant women and breast-feeding women, or women who plan a pregnancy while on medication
2. Severe liver impairment
3. Current depression or moderate to severe depression within last six months
4. People with a past history of eating disorders
5. People with a past history of psychotic disorder
6. People with a history of alcohol or illegal drug use within the past six months
7. People taking medication that may interact with SJW

Date of first enrolment
21/02/2006

Date of final enrolment
31/08/2006

Locations

Countries of recruitment
United Kingdom

Study participating centre
BMS
Oxford
United Kingdom
OX3 OBP

Sponsor information

Organisation
Oxford Brookes University (UK)

Sponsor details
Gipsy Lane
Headington
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Sponsor type
University/education

ROR
https://ror.org/04v2twj65

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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	01/06/2009		Yes	No