

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	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 24/02/2006	Overall study status Completed	☐ Protocol
Last Edited 18/01/2012	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2009		Yes	No