# 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	Recruitment status  No longer recruiting	Prospectively registered	
08/02/2006		Protocol	
Registration date	Overall study status Completed	Statistical analysis plan	
24/02/2006		[X] Results	
<b>Last Edited</b> 18/01/2012	Condition category  Mental and Behavioural Disorders	Individual participant data	

# Plain English summary of protocol

Not provided at time of registration

# **Contact information**

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

# 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 Oxford United Kingdom OX3 OBP ifrancis@brookes.ac.uk

#### 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