

The effect of hydrocortisone on desire to smoke and tobacco withdrawal symptoms

Submission date	Recruitment status	<input checked="" type="checkbox"/> Prospectively registered
30/04/2007	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
24/05/2007	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
03/03/2015	Mental and Behavioural Disorders	

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

Clinical Trials Information System (CTIS)
2007-002203-40

Protocol serial number

7.0056

Study information

Scientific Title

The effect of hydrocortisone on desire to smoke and tobacco withdrawal symptoms

Study objectives

That giving oral hydrocortisone (on the first day of smoking abstinence), may significantly reduce the desire to smoke and reduce tobacco withdrawal symptoms among temporarily abstinent smokers, relative to a placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Wandsworth Research Ethics Committee, 20/07/2007, ref: 07/Q0803/97

Study design

Randomised double-blind placebo-controlled study, within-subject balanced cross-over design

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Nicotine dependence/smoking cessation

Interventions

40 mg hydrocortisone (HC) versus 20 mg HC versus placebo. Each participant will only receive a single dose of each treatment on waking and will be followed-up just on the afternoon after they have taken the tablet.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Hydrocortisone

Primary outcome(s)

Reports of desire to smoke and tobacco withdrawal, these will be measured prior to abstinence on waking and then after two hours, four hours and six hours. On each of the three treatment days these symptoms will be measured at the same time points.

Key secondary outcome(s)

No secondary outcome measures

Completion date

30/11/2008

Eligibility

Key inclusion criteria

1. Male and female smokers aged 18 to 65 years
2. Have been smoking at least ten cigarettes a day for at least three years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Key exclusion criteria

1. Those receiving psychiatric treatment
2. Those currently taking corticosteroids
3. Those with cautions for using oral corticosteroids will also be excluded as follows:
 - 3.1. Pregnant
 - 3.2. Planning a pregnancy or breastfeeding
 - 3.3. Heart problems
 - 3.4. Patient suffers from tuberculosis or has had it in the past
 - 3.5. Stomach ulcer or other digestive problem
 - 3.6. Shingles or a herpes infection in the eye
 - 3.7. Muscle weakness (myopathy) after using steroids in the past
 - 3.8. Diabetic
 - 3.9. High blood pressure
 - 3.10. Glaucoma
 - 3.11. Corneal perforation
 - 3.12. Significant impairment of renal or liver function
 - 3.12. Myasthenia gravis
 - 3.14. Osteoporosis
 - 3.15. Thyroid problems
 - 3.16. Epilepsy

Date of first enrolment

01/12/2007

Date of final enrolment

30/11/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

St George's University of London

London

United Kingdom

SW17 0RE

Sponsor information

Organisation

St George's University of London (UK)

ROR

<https://ror.org/040f08y74>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (ref: C8641/A8419)

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	01/07/2011		Yes	No