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

Submission date	Recruitment status	[X] Prospectively registered
30/04/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/05/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] 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

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Additional identifiers

EudraCT/CTIS number
2007-002203-40

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/12/2007

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
50

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
England

United Kingdom

Study participating centre
St George's University of London
London
United Kingdom
SW17 0RE

Sponsor information

Organisation
St George's University of London (UK)

Sponsor details
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Sponsor type
University/education

Website

https://portal.sgul.ac.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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