The actions of phloridzin on sodium ion transporters and potential difference in nasal airway epithelium.

Submission date	Recruitment status	☐ Prospectively registered
30/09/2005	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2005	Stopped	Results
Last Edited	Condition category	☐ Individual participant data
05/04/2011	Respiratory	Record updated in last year

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

 ${\bf Clinical Trials. gov\ number}$

Secondary identifying numbers

N0236143719

Study information

Scientific Title

Study objectives

To determine whether nasal application of phloridzin, a sodium-glucose co-transporter (SGLT-1) inhibitor, alters nasal potential difference demonstrating SGLT-1 function.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Wandsworth REC (UK)

Study design

In vivo pharmacological study

Primary study design

Interventional

Secondary study design

Other

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Respiratory: Chronic obstructive pulmonary disease (COPD)

Interventions

Nasal potential difference: between the 'sensing' electrode in contact with the nasal epithelium, and the 'reference' electrode, a butterfly needle inserted under the skin of the forearm, is measured. Phloridzin in Ringer's solution will then be additionally perfused onto the nasal epithelium and any further change in nasal PD recorded. On a second visit a repeat of the above protocol will be carried out with phloridzin followed be amiloride.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

phloridzin

Primary outcome measure

Changes in the measured nasal potential difference with phloridzin

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/10/2002

Completion date

01/12/2007

Reason abandoned (if study stopped)

Not a clinical trial

Eligibility

Key inclusion criteria

Healthy, non-smoking volunteers with normal nasal mucosa and random plasma glucose <7mmol /l.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

10

Key exclusion criteria

- 1. Nasal disease
- 2. Diabetes mellitus
- 3. Pregnancy

Date of first enrolment

01/10/2002

Date of final enrolment

01/12/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre St George's Hospital London United Kingdom SW17 ORE

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

St George's Healthcare NHS Trust (UK)

Funder Name

No External Funding

Funder Name NHS R&D Support Funding

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration