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Clinical trial of V3381 in chronic cough

Submission date 08/09/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 13/12/2010	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 06/12/2019	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Ashley Woodcock

Contact details
Education and Research Centre
Wythenshawe Hospital
Southmoor Road
Manchester
United Kingdom
M23 9LT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01401673

Secondary identifying numbers
V001; G0701918

Study information

Scientific Title
Phase II open label pilot study of V3381 in chronic cough

Study objectives
Cough reflex hypersensitivity, demonstrated in chronic cough patients, is due to a phenomenon known as central sensitisation, mediated by the N-methyl d-aspartate (NMDA) receptor.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West Research Ethics Committee approved on the 28th August 2009 (ref: 09/H1010/39)

Study design
Non-randomised single arm open-label study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic cough

Interventions
Patients received treatment with V3381 for 8 weeks and attended for study visits after 1 week, 2 weeks, 4 weeks and 8 weeks of treatment. A validated cough-specific quality of life questionnaire (CQLQ) was completed by patients after 2 weeks, 4 weeks and 8 weeks of treatment. Twenty-four hour objective cough monitoring was performed at baseline and after 4 and 8 weeks of treatment using a custom-built recording device. All adverse events were documented.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)

V3381

Primary outcome measure
Objective cough frequency over 24 hours at 8 weeks of treatment compared to baseline.

Secondary outcome measures
1. Objective cough frequency over 24 hours at 4 weeks of treatment compared to baseline
2. Cough-related quality of life at 2, 4 and 8 weeks of treatment compared to baseline
3. Treatment-related adverse events

Overall study start date
01/10/2009

Completion date
01/10/2010

Eligibility

Key inclusion criteria
1. Male or female 18 - 75 years of age
2. Females must be of non child-bearing potential (i.e., surgically sterilised or greater than 1 year post-menopause). Male patients who are sexually active with a female partner of child-bearing potential must agree to use a barrier method of contraception for the duration of the study.
3. Chronic cough (greater than 8 weeks)
4. Normal chest X-ray
5. Normal lung function
6. Idiopathic or treatment resistant cough, defined as a cough for which no objective evidence of an underlying trigger can be determined after investigation (idiopathic) or a cough that is unresponsive to 8 weeks of targeted treatment for identified underlying triggers including reflux disease, asthma and post-nasal drip (treatment-resistant)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

Key exclusion criteria
1. Recent upper respiratory tract infection (less than 4 weeks)
2. Pregnancy/breast-feeding
3. Current smokers or ex-smokers with less than 6 months abstinence or cumulative history of

greater than 10 pack years
4. Current treatment with angiotensin converting enzyme (ACE) inhibitors
5. Drug or alcohol abuse
6. Uncontrolled hypertension (i.e., greater than 140/90 mmHg despite adequate medical therapy)
7. Any cardiovascular condition that would be a contra-indication to the use of sympathomimetic amines (e.g. active angina)
8. Any clinically significant neurological disorder
9. Prior renal transplant, current renal dialysis
10. Any clinically significant or unstable medical or psychiatric condition that would interfere with the patient's ability to participate in the study
11. Increased risk of seizures (defined as a history of seizure disorder, family history of seizures and history of head trauma that resulted in loss of consciousness or concussion)
12. Any malignancy in the past 2 years (with the exception of basal cell carcinoma)
13. Use of opioids, anticonvulsants, antidepressants (particularly monoaminde oxidase [MAO] inhibitors). Patients currently taking drugs in these classes for chronic cough may have them discontinued prior to entry into the study. Selective serotonin reuptake inhibitors should be discontinued at least 4 weeks prior to study; all other prohibited medications should be discontinued 2 weeks prior to study. Patients should not be taking NMDA-receptor antagonists or sympathomimetics during the study period.
14. Any clinically significant abnormal laboratory test result(s)
15. Serum creatinine laboratory value greater than 1.5 x upper limit of normal (ULN) reference range (after adjustment for age) or estimated creatinine clearance less than 60 ml/min
16. Total bilirubin greater than upper limit of normal reference range (with the exception of Gilbert's syndrome) and/or alanine transaminase (ALT) greater than 1.5 times upper limit of normal reference ranges (after adjustment for age)

Date of first enrolment
01/10/2009

Date of final enrolment
01/10/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Education and Research Centre
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
Vernalis (R&D) Ltd (UK)

Sponsor details
Oakdene Court
613 Reading Road
Winnersh
Berkshire
United Kingdom
RG41 5UA

Sponsor type
Industry

Website
http://www.vernalis.com/

ROR
https://ror.org/027p78k86

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) (ref: G0701918)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

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?
HRA research summary			28/06/2023	No	No