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Hookah trial: the efficacy of varenicline in achieving abstinence among hookah smokers

Submission date
20/11/2015

Recruitment status
No longer recruiting

Registration date
01/12/2015

Overall study status
Completed

Last Edited
07/01/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Hookahs are water pipes used to smoke tobacco. It has many of the same health risks as cigarette smoking. The number of young people taking up the habit has increased across the globe, including in the United States, and it continues as a common and traditional form of smoking tobacco in Pakistan. A range of behavioural and pharmacological (drug) therapies is available to support people in quitting cigarette smoking, however, little evidence exists on whether they work to help people who want to stop hookah smoking. The aim of this study is to test how well the drug varenicline performs at helping people quit hookah smoking when combined with behavioural support by using a biochemically validated technique (measuring carbon monoxide levels) to check for the absence of smoking.

Who can participate?
Adults who have been hookah smokers on a daily basis for at least six-months and are willing to quit smoking.

What does the study involve?
Participants are randomly allocated to one of two different groups. Those in group 1 are given varenicline and behavioural support. Those in group 2 are given a placebo and behavioural support. All participants then have their carbon monoxide levels measured after 5 weeks, 12 weeks and 25 weeks of the study starting. Participants are also asked to report on whether they have stopped smoking, whether they lapsed early or late on into the study (even if they smoked just the once).

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Three district hospitals in Punjab, Pakistan

When is the study starting and how long is it expected to run for?
July 2015 to January 2017

Who is funding the study?
Pfizer (USA)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
WI194558

Study information

Scientific Title
The efficacy of varenicline in achieving abstinence among hookah smokers: a two-arm, double blind, randomised, placebo controlled trial

Acronym
Hookah Trial

Study objectives
Is varenicline co-administered with behavioural support more efficacious in achieving six-month' s continuous abstinence from all forms of tobacco smoking among hookah smokers than a combination of placebo and behavioural support?

The aim is to assess the efficacy of varenicline when added to behavioural support for smoking cessation, by measuring biochemically validated continuous abstinence from week 5 to 25 in hookah smokers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. National Bioethics Committee (NBC) Pakistan
2. Health Sciences Research Governance Committee (HSRGC)

Study design
Two-arm, double-blind, randomised, placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
The efficacy of varenicline (either alone or in combination with other therapies) in hookah cessation is currently unknown.

Interventions
Once enrolled, participants in the trial will be randomised to receive behavioural support either with varenicline or with placebo tablets. A quit date will be set one week after enrolling in the trial. The components of the treatment arms are described below.

As part of a previous smoking cessation trial conducted in Pakistan (ASSIST trial),26 we have already developed an effective behavioural support intervention to help people to quit smoking. However, this will need adaptation to incorporate hookah smoking, in particular addressing those specific behavioural determinants, which are associated with hookah smoking. Therefore, with the help of an expert panel (comprising of a behavioural scientist, tobacco cessation specialist, public health academic, and an epidemiologist), we will undertake an iterative process to identify the required modifications and model these into the existing intervention, in order to make it suitable for hookah smokers. We will also modify the associated materials and then pre-test them with the expert panel.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Varenicline

Primary outcome measure
Self-reported continuous abstinence for at least six months (no smoking allowed in the seven days prior to each of the three assessments) which is biochemically verified by a CO level of <10ppm measured by MicroCO (Micro Medical ltd., United Kingdom) at week 5, week 12, and week 25. When a participant self-reports abstinence with an elevated CO level of >10ppm on any of the three assessments, we will use salivary kits for checking cotinine in such cases. Depending on the findings of cotinine, the participant will categorised as smoker or not.

Secondary outcome measures
1. Point abstinence, defined as a self-report of not smoking in the previous 7 days and verified by a CO level of <10ppm, at week 5, week 12, and week 25
2. Early-lapse, defined by a self-report of smoking (even once) after the quit date but having point abstinence at week 5
3. Late-lapse, defined by a self-report of smoking (even once) between week 5 and week 12 but showing point abstinence at week 5 and week 12
4. Early-relapse, defined by a point abstinence at week 5 but a smoking status in later assessments
5. Late-relapse, defined by a point abstinence at week 5 and week 12 but a smoking status at week 25
6. Differences in the point and continuous abstinences, lapses and relapses between exclusive hookah-smokers and those that combine it with other forms of smoking tobacco

All outcomes will be measured before and after the intervention in each of the study's arms.

Overall study start date
01/07/2015

Completion date
01/01/2017

Eligibility

Key inclusion criteria
1. Adults (both males and females) at least 18 years of age
2. Smoked hookah on a daily basis for at least six months (validated by breath carbon monoxide [CO] > 10ppm). Daily smoking is defined if person smokes > 25 days in a month
3. Motivated to give up all forms of smoking completely

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
510

Total final enrolment
510

Key exclusion criteria
People will be excluded if they:
1. Have used any pharmacotherapy for tobacco dependence (including nicotine replacement therapy and electronic cigarettes) in the last 30 days
2. Are pregnant, lactating, or planning to become pregnant
3. Have a medical condition requiring hospitalisation
4. Have used varenicline in the past and had an allergic reaction
5. Have a history of heart disease including unstable angina, untreated cardiac arrhythmia, myocardial infarction, or have a cardiac procedure (last three months)
6. Have uncontrolled hypertension or a history of stroke
7. Have a history of chronic kidney disease
8. Have a history of epilepsy
9. Have suicidal ideation or a history of self-harm
10. Have a history of schizophrenia, psychosis, or bipolar disorder
11. Current moderate or severe depression
12. Current use of smokeless tobacco
13. Active use of substances (including alcohol misuse) other than tobacco

Date of first enrolment
01/01/2016

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
Pakistan

Study participating centre
District Headquarters Hospital, Chakwal
Chakwal
Pakistan
48800

Study participating centre
District Headquarters Hospital, Khushab
Khushab
Pakistan
41000

Study participating centre
District Headquarters Hospital, Mandi Bahauddin
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Sponsor information

Organisation
University of York

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Sponsor type
University/education

Website
http://www.york.ac.uk/

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Industry

Funder Name
Pfizer

Alternative Name(s)
Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan

Intention to publish date
01/01/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/01/2017		Yes	No
Results article		27/09/2018	07/01/2022	Yes	No