

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

<b>Submission date</b> 20/11/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 01/12/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/01/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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?  
Dr Raana Zahid  
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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),<sup>26</sup> 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 be 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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50400

## **Sponsor information**

**Organisation**

University of York

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University/education

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**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?
<a href="#">Protocol article</a>	protocol	11/01/2017		Yes	No
<a href="#">Results article</a>		27/09/2018	07/01/2022	Yes	No