

The efficacy of e-cigarettes compared with nicotine replacement therapy, when used within the UK stop smoking service

Submission date 02/04/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 07/04/2015	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/06/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-electronic-cigarettes-with-nicotine-replacement-therapy-to-stop-smoking-tec>

Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

HTA 12/167/135

Study information

Scientific Title

A randomised controlled trial to examine the efficacy of e-cigarettes compared with nicotine replacement therapy, when used within the UK stop smoking service

Acronym

TEC (Trial of Electronic Cigarettes)

Study objectives

To determine the 12-month sustained biochemically validated abstinence rates in smokers using electronic cigarettes (EC) compared to smokers using standard nicotine replacement therapy (NRT).

More details can be found at <http://www.nets.nihr.ac.uk/projects/hta/12167135>

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee London Camden & Islington, 14/LO/2235, 19/12/2014

Study design

Multicentre pragmatic randomised controlled trial

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

Smoking cessation

Interventions

Smokers who want help to quit smoking will be individually randomised to receive usual care (UC; a choice of NRT combined with usual care behavioural support provided by a Stop Smoking Service) or EC with the same behavioural support.

Intervention Type

Device

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Electronic cigarettes, nicotine replacement therapy

Primary outcome measure

Carbon monoxide (CO) validated sustained abstinence rates at 52 weeks post–target quit date (TQD)

Secondary outcome measures

1. CO validated sustained abstinence rates at 4 and 24 weeks post–TQD
2. 7-day point prevalence abstinence at 4, 24 and 52 weeks
3. Smoking reduction in participants who did not achieve full abstinence
4. Treatment ratings
5. Adverse reactions
6. Cost-efficacy of the interventions

Overall study start date

01/04/2015

Completion date

31/03/2018

Eligibility**Key inclusion criteria**

1. Aged 18 or over
2. Current smoker accessing the stop smoking service
3. Able to read/write/understand English

Participant type(s)

Other

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

886

Total final enrolment

886

Key exclusion criteria

1. Pregnant or breastfeeding
2. Strong preference to use or not to use NRT or EC in their quit attempt
3. Enrolled in other interventional research
4. Currently using NRT or EC

Date of first enrolment

15/04/2015

Date of final enrolment

01/12/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Queen Mary University of London

United Kingdom

E1 4NS

Study participating centre

Leicester Stop Smoking Service

United Kingdom

LE1 6TH

Study participating centre

East Sussex Stop Smoking Service

United Kingdom

TN38 9UH

Sponsor information

Organisation

Queen Mary University of London (QMUL)

Sponsor details

Queen Mary Innovation Centre
5 Walden Street
London
England
United Kingdom
E1 2EF

Sponsor type

University/education

ROR

<https://ror.org/026zzn846>

Funder(s)**Funder type**

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications**Publication and dissemination plan**

The results of the study will be published in a peer-reviewed scientific journals and presented at conferences.

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/02/2019		Yes	No
Results article	results	01/08/2019	23/08/2019	Yes	No
Plain English results			25/02/2020	No	Yes
Protocol file	version 3.0	08/04/2015	18/08/2022	No	No
Statistical Analysis Plan	version 1.0	08/01/2018	18/08/2022	No	No
HRA research summary			28/06/2023	No	No
Results article	Costs effectiveness	04/12/2019	24/06/2025	Yes	No