ISRCTN60477608 https://doi.org/10.1186/ISRCTN60477608

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

Registration date
07/04/2015

Overall study status
Completed

Last Edited
18/08/2022

Condition category
Mental and Behavioural Disorders

✓ Prospectively registered
✓ Protocol added
✓ SAP added
✓ Results added
? Raw data not yet added
✓ Study completed

Plain English Summary
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

IRAS number

ClinicalTrials.gov number

Protocol/serial number

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 hypothesis
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

Condition
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

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

Overall study end date
31/03/2018

Eligibility

Participant 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

Participant 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

Recruitment start date
15/04/2015

Recruitment end date
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