ISRCTN95345566 https://doi.org/10.1186/ISRCTN95345566

Evaluation of short-term safety and use patterns of an e-cigarette

Submission date
22/06/2013

Recruitment status
No longer recruiting

Registration date
01/07/2013

Overall study status
Completed

Last Edited
11/04/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Electronic cigarettes (e-cigarettes) have gained popularity over the last several years. The method used to make e-cigarettes has been evolving rapidly. Only in the last few years have researchers begun to study the health risks and benefits, blood levels of nicotine (a chemical present in tobacco), patterns of use, niceness and craving and withdrawal remedies of e-cigarettes. These studies have shown great variability in various factors among various e-cigarette brands for tobacco cigarette smokers. This study will test a new generation e-cigarette, the NJOY King (NJOY, Scottsdale, AZ). It is a single use unit that resembles a traditional cigarette and delivers approximately 150 puffs. The main aim is to find out the short-term effects of using the NJOY Kings e-cigarettes on various health factors and well as on craving for cigarettes and withdrawal. This study will also test the participants usage patterns for cigarettes and NJOY King e-cigarettes during a one-week period in which they can use each freely.

Who can participate?
A total of 30 male and female regular cigarette smokers aged 18-65 years will be enrolled in the study. Eligibility will be determined through a telephone screen and a screening visit at the clinic.

What does the study involve?
The study includes three visits to the clinic spaced approximately one week apart. Participants who pass the screening visit will return to the clinic for Visit 2 in which they will use the NJOY King e-cigarette for about 20 minutes before taking home enough to last till Visit 3, one week later. They will be instructed to use as many or as few as they like during the week. Participants will keep a daily record of number of tobacco cigarettes smoked and number of e-cigarette puffs taken. They will return to the clinic for Visit 3 after 12 hours of not using any form of nicotine to make sure that they have no nicotine left in their bloodstream. Eligible participants will then participate in two series of 10 puffs of NJOY Kings spaced one hour apart. During the 2.5 hours of the testing day, the following will be measured: 1) heart rate, 2) carbon monoxide (breath test), 3)blood will be tested for nicotine levels, 4) craving for cigarettes and withdrawal symptoms.

What are the possible benefits and risks of participating?
Participants in this study should not expect any benefits other than the knowledge that they have contributed to medical science. The most frequently reported side effects of orally given nicotine are: mouth and tongue irritation, sore throat, coughing, feeling ill (or nauseated), stomach discomfort, diarrhea, indigestion/heartburn, headache, gas or hiccups. Symptoms of nicotine over-dosage may include vomiting, diarrhea, nausea, dizziness, increased saliva, abdominal pain, headache, weakness or rapid heartbeat. Blood drawing may cause bruising, swelling, or pain at the site where the blood is drawn. There is also a small chance of infection. There is always a chance that an unexpected side effect may happen to people who use the NJOY King e-cigarette.

Where is the study run from?
The study will be run at LA Clinical Trials in Burbank, CA, USA.

When is the study starting and how long is it expected to run for?
The study will start recruiting early to mid-2013. All study visits are expected to be completed within 2 months.

Who is funding the study?
Funding has been provided by NJOY, Inc., the manufacturer of ENJOY Kings e-cigarettes, USA.

Who is the main contact?
Dr Mitchell Nides
minds@laclinicaltrials.com

Contact information

Type(s)
Scientific

Contact name
Dr Mitchell Nides

Contact details
4116 W. Magnolia Blvd. Suite 100
Burbank
United States of America
91505
818-526-7645
mnides@laclinicaltrials.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01898169

Secondary identifying numbers
NJ-001_LACT

Study information

Scientific Title
An open-label evaluation of plasma nicotine, carbon monoxide, heart rate, craving and withdrawal after acute use of the NJOY King e-cigarette in the clinic, following a one-week actual use pilot study

Study objectives
It is hypothesized that smokers who take 10 puffs from an NJOY King e-cigarette after abstaining from any nicotine containing products for 12 hours will show short-term increases in their blood nicotine levels and heart rate, their craving for cigarettes will decrease, and their carbon monoxide levels will not be affected. A secondary hypothesis is that smokers who test NJOY Kings for a week will reduce the number of traditional cigarettes they smoke.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Essex Institutional Review Board (IRB), Lebanon, NJ. March, 27, 2013

Study design
Single-center three-week open-label design

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

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
Nicotine dependence

Interventions
This is an open-label study of the NJOY Kings e-cigarette. Subjects will test the NJOY King during a one week period. They will instructed to use the e-cigarettes as often as they like at

times that they feel like smoking, but they will not be asked to use a specific number of e-cigarettes, just to use as they see fit. The third visit is the conclusion of the study, there is no additional follow-up, except for open adverse events, which will be followed until resolution.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
On the Visit 3 testing day the changes in blood nicotine levels, heart rate, carbon monoxide, craving for cigarettes and nicotine withdrawal symptoms pre- and post 10-puff sessions of using the NJOY King after 12 hours of abstinence from nicotine.

Secondary outcome measures
Changes from baseline in number of cigarettes per day during the one week NJOY testing period. Subjects perceptions on their use of the NJOY e-cigarettes during the one week testing period.

Overall study start date
01/04/2013

Completion date
01/07/2013

Eligibility

Key inclusion criteria
1. Consent: Demonstrates understanding of the study and willingness to participate as evidenced by voluntary written informed consent and has received a signed and dated copy of the consent form.
2. Age:18-65 years
3. Body Mass Index: Subject has a BMI within the range of 18-35 kg/m2
4. Compliance: Understands and is willing, able, and likely to comply with all the study procedures and restrictions.
5. General Health: Good general health with (in the opinion of the study doctor) no clinically significant and relevant abnormalities of medical history
6. Smoking status: Cigarette smokers who smoke at least 10 cigarettes per day and are not currently attempting to quit smoking
7. Carbon Monoxide: CO level greater than 10ppm at the screening visit and less than 10ppm at Visit 3
8. Contraception: Females of childbearing potential who are, in the opinion of the investigator, practicing a reliable method of contraception

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Pregnancy: Women who are pregnant or who have a positive urine pregnancy test
2. Breast-feeding: Women who are breast-feeding
3. Allergy/Intolerance: Known allergy to heparin, or allergy or suspected intolerance or hypersensitivity to the study materials (or closely related compounds) or any of their stated ingredients
4. Clinical Study/Experimental Medication: Participation in another clinical study or receipt of an investigational drug within 30 days of the screening visit
5. Previous participation in this study
6. E-cigarette use: Any use of an e-cigarette within 14 days of the screening visit
7. Substance Abuse: Positive drugs of abuse urine screening at the screening and any subsequent visits. Tested drugs include cocaine, amphetamines, methamphetamines, cannabis, opiates, (morphine, heroin), phencyclidine, barbiturates, benzodiazepine.
8. Alcohol abuseSelf-reported use of more than 21 drinks per week. A drink is defined as 1.5 oz of spirits (e.g. whiskey, vodka), 12 oz of beer, or 5 oz of wine.
9. Personnel: An employee of the sponsor or the study site or members of their immediate family
10. Prior Concomitant Medications: Use of any prescription psychoactive medication (such as but not limited to antidepressants, anti-psychotics, anxiolytics) within 14 days of the Testing visit. Use of any nicotine replacement therapy within 30 days of the Screening Visit.

Date of first enrolment
01/04/2013

Date of final enrolment
01/07/2013

Locations

Countries of recruitment
United States of America

Study participating centre
4116 W. Magnolia Blvd. Suite 100
Burbank
United States of America
91505

Sponsor information

Organisation
NJOY Inc. (USA)

Sponsor details
15211 North Kierland Blvd.
Suite 200
Scottsdale
United States of America
85254

Sponsor type
Industry

ROR
https://ror.org/00g2e9181

Funder(s)

Funder type
Industry

Funder Name
NJOY Inc. Scottsdale, AZ, USA

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?
Results article	results	01/03/2014	11/04/2019	Yes	No