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Increasing the dose of nicotine replacement treatment to individual needs

Submission date
16/03/2017

Recruitment status
No longer recruiting

Registration date
18/05/2017

Overall study status
Completed

Last Edited
06/08/2019

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
Nicotine replacement treatment (NRT) is widely used to help people quit smoking, but it's not effective for everyone. This may be, in part, because many smokers receive less nicotine from NRT than smoking. There is some evidence that higher dosing and the use of NRT before actually quitting smoking may help. This is because nicotine from NRT may weaken the association between smoking behaviour and the nicotine reward from cigarettes, and in turn reduce the desire to smoke. A potentially promising approach would be to increase the NRT dose before quitting, with the aim of achieving nicotine levels which make smoking unrewarding or even unpleasant. The aim of this study is to examine the acceptability, safety, and potential efficacy of an personalized program which increases NRT (iNRT) dosing to help people quit smoking.

Who can participate?
Adult smokers who want to quit and are willing to use nicotine patches.

What does the study involve?
All participants are given nicotine patches to use for four weeks before their target quit date and for four weeks afterwards. In the four weeks before they quit, the dose of nicotine patches is increased every week if the smoker does not report any side effects, such as feeling sick. The maximum dose given can be up to 84mg/day. Over the four weeks after the quit date, the patch dose is reduced to standard levels (21mg/day). The number of participants who progress through each stage of the dosing schedule are recorded as well as those who are sticking to the treatment. In addition, participants are interviewed about changes in smoking rate and enjoyment of smoking, withdrawal symptoms, and the quit rate at 4 weeks after the target quit date.

What are the possible benefits and risks of participating?
Participants may benefit from being able to successfully quit smoking. there are no notable risks involved with participating. If participants experience any severe side effects from the nicotine patch, they will be asked to either stop altogether or reduce the dose.

Where is the study run from?
Emphysema Foundation (Argentina)

When is the study starting and how long is it expected to run for?
December 2016 to August 2018

Who is funding the study?
Global Research Awards for Nicotine Dependence (UK)

Who is the main contact?
1. Dr Dunja Przulj (scientific)
2. Dr Luis Wehbe (scientific)

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1.1 10 Oct 2016

Study information

Scientific Title
Increasing the dose of Nicotine Replacement Treatment to individual needs: A pilot study

Acronym
iNRT

Study objectives
The aim of this study is to examine the feasibility and acceptability of increasing the dose of nicotine patches used prior to a smokers target quit date (TQD) in order to establish what proportion of smokers are likely to progress to different levels of dose increase and what, if any, side effects they may report.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Joint Commission on Health Research (Comisión Conjunta de Investigación en Salud- CCIS), Beunos Aires, Argentina, 24/01/2017, ref: 2919/1419/2016

Study design
Open-label single-site non-randomised pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

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
Smoking cessation

Interventions
Smokers wanting to give up will be given nicotine patches to use for 4 weeks prior to their target quit day and for 4 weeks during their quit attempt. In the four weeks prior to their target quit day, the dose of nicotine patches will increase each week if the smoker does not report any reaction to it (e.g. nausea). The maximum dose used could be up to 84mg/day (i.e. the

participant would wear 4 patches a day). Over the 4 weeks after the quit day, the patch dose will be reduced to standard levels (21mg/day, i.e. 1 patch per day). The total duration of the intervention is 8 weeks. There is no further follow-up of participants after this.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
21mg/24hr Nicotine Transdermal Patch

Primary outcome measure
Feasibility of the intervention is assessed by recording the proportion of participants who progress through each stage of increased dosage (42mg, 63mg and 84mg) over the four weeks prior to their Target Quit Day.

Secondary outcome measures
1. Adherence to treatment will be assessed by examining the frequency of patch use over the 8 weeks and the number of participants who stop using their patches over the 8 weeks
2. Acceptability and helpfulness of the intervention will be measured by asking participants to rate (1-5) how helpful they found their patch over the last week, at each session; and by looking at the frequency of any adverse effects and their intensity
3. Potential efficacy of the intervention will be measured by examining validated abstinence rates at the end of the 8 weeks, changes in carbon monoxide readings, cigarette consumption, enjoyment of smoking and withdrawal symptoms over the first 4 weeks prior to the TQD; and changes in withdrawal symptoms over the 8 weeks

Overall study start date
14/12/2016

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. Aged 18-65 years of age
2. Daily smoker
3. Seeking treatment to quit smoking and willing to use nicotine patches

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
50

Total final enrolment
50

Key exclusion criteria
1. Pregnant/breastfeeding or planning to conceive in the next 3 months
2. Previous adverse reaction to the nicotine patch
3. Serious medical condition including, cancer and psychiatric illness
4. History of Myocardial infarction
5. Cannot read, write or understand Spanish
6. Current involvement in other interventional research

Date of first enrolment
01/04/2017

Date of final enrolment
31/07/2017

Locations

Countries of recruitment
Argentina

Study participating centre
Emphysema Foundation (Fundación Enfisema)
Carlos Alvear 3345
Mar del Plata
Buenos Aires
Argentina
CP7600

Sponsor information

Organisation
Fundación Enfisema

Sponsor details

Carlos Alvear 3345, Mar del Plata
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Sponsor type
Other

Funder(s)

Funder type
Research organisation

Funder Name
Global Research Awards for Nicotine Dependence (GRAND)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
31/08/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Dunja Przulj, d.przulj@qmul.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2019	06/08/2019	Yes	No