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Effectiveness of co-oximetry and minimum advice for smoking cessation in kidney transplant recipients

Submission date
05/06/2015

Recruitment status
No longer recruiting

Registration date
02/07/2015

Overall study status
Completed

Last Edited
17/08/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
In order to modify a problem behaviour, for example smoking, over-eating or drinking too much, a person has to be motivated to make that change. Many people are in denial of their problem behaviour and may not see their behaviour as problematic; these people are considered to be in the precontemplation stage. In contrast, some people are willing to admit that they may have a problem, are comtemplating changing their behaviour but are ambivalent about doing so. Here, we are looking at how successful measuring exhaled carbon monoxide (MO) along with brief advice for smoking cessation helps smoking kidney recipients to stop smoking, increase their motivation to stop smoking or reduce the number of cigarettes that they smoke per day. We will be comparing the results of this intervention for people at the contemplation stage compared with the precontemplation stage of change. We will also be looking at how well it works compared to when people are given brief advice alone.

Who can participate?
Smoking kidney transplant recipients who are prepared to give up smoking, are contemplating it or are in the precontemplation stage.

What does the study involve?
Participants are randomised into one of two groups. Those in group 1 are assigned as controls. Those in group 2 are assigned to the intervention group. All participants are given a brief advisory session about giving up smoking; this is individually tailored and provides information about the health risks of smoking and the main advantages of quitting the habit. Participants in the intervention group also have the oxygen carrying state of their haemoglobin (protein in red blood cells that carry oxygen) measured using a CO-oximeter; this detects the amount of carbon monoxide (CO) that the participant has in their body. All participants from both groups are followed up 3 months, 6 months and 9 months later. At each of these visits, the anti-smoking advice is repeated for the control group and anti-smoking advice plus CO-oximetry for the intervention group. How well the intervention performs is assessed at 3, 6, 9 and 12 months. This includes looking at how many participants have reduced the amount of cigarettes they smoke, or stop smoking altogether.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University Hospital Complex A Coruña (Spain)

When is the study starting and how long is it expected to run for?
December 2012 to December 2015

Who is funding the study?
Instituto de Salud (National Institute of Health) Carlos III (Spain)

Who is the main contact?
Dr Salvador Pita- Fernández

Contact information

Type(s)
Scientific

Contact name
Dr Salvador Pita-Fernández

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15006

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effectiveness of co-oximetry and minimum advice for smoking cessation in kidney transplant recipients: a randomized controlled trial

Study objectives

To compare, in smoking kidney transplant recipients in the contemplation or precontemplation stage of change, the effectiveness of the measurement of exhaled carbon monoxide (CO) plus brief advice for smoking cessation, compared with brief advice alone, with respect to:
1. Smoking cessation
2. Increased motivation to quit smoking
3. Reduction in the number of cigarettes smoked per day

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comité ético de investigación clínica de Galicia, ref: 2011/061

Study design
Randomized controlled trial (open, with blinded evaluation)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Smoking in kidney transplant recipients

Interventions
Patients will be randomized to:
1. The control group (brief advice for smoking cessation)
or
2. Intervention (brief advice + exhaled CO measurement)

Intervention Type
Behavioural

Primary outcome measure
The effectiveness will be evaluated at 6 and 12 months by smoking cessation confirmed by nicotine test results.

Secondary outcome measures

Abandoned self-declared (by number of cigarettes smoked per day and changes in the dependency stage).

Overall study start date
01/12/2012

Completion date
31/12/2015

Eligibility

Key inclusion criteria
Smoking kidney transplant recipients, in preparation stage, precontemplation and contemplation stage of change, that give their consent to participate

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
n= 122 (alfa=95%, Power=80% Loss=10%.Difference to detect 12%)

Total final enrolment
122

Key exclusion criteria
Patients with terminal illness or mental disability.

Date of first enrolment
01/12/2012

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Spain

Study participating centre
University Hospital Complex A Coruña (Sergas Complejo Hospitalario Universitario de A Coruña)
As Xubias de Arriba 84

A Coruña
Spain
15006

Sponsor information

Organisation
Complejo Hsopitalario Universitario de A Coruña

Sponsor details
As Xubias de Arriba 84
A Coruña
Spain
15006

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/044knj408

Funder(s)

Funder type
Government

Funder Name
Instituto de Salud Carlos III

Alternative Name(s)
SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, ISCIII

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/04/2016		Yes	No
Results article		23/09/2020	17/08/2023	Yes	No