

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

Submission date 05/06/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 02/07/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/08/2023	Condition category Mental and Behavioural Disorders	☐ 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 contemplating 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

Contact details
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15006

Additional identifiers

Protocol serial number
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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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 Hospitalario Universitario de A Coruña

ROR

<https://ror.org/044knj408>

Funder(s)

Funder type

Government

Funder Name

Instituto de Salud Carlos III

Alternative Name(s)

SaludISCI, Instituto de Salud Carlos III, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, La misión del Instituto de Salud Carlos III (ISCI), ISCI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Spain

Results and Publications

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?
Results article		23/09/2020	17/08/2023	Yes	No
Protocol article	protocol	01/04/2016		Yes	No