

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

<b>Submission date</b> 05/06/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 02/07/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/08/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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**  
Complejo Hospitalario Universitario de A Coruña  
Clinical epidemiology and biostatistics Unit  
As Xubias de Arriba 84  
A Coruña  
Spain  
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 Hospitalario 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)

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, ISCI

### 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?
<a href="#">Protocol article</a>	protocol	01/04/2016		Yes	No
<a href="#">Results article</a>		23/09/2020	17/08/2023	Yes	No