

Clinical trial on the efficacy of exhaled carbon monoxide measurement plus brief physician's advice for smoking cessation

Submission date 16/06/2010	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 21/07/2010	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 12/10/2012	Condition category Other	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Miss Joana Ripoll

Contact details
C/Reina Esclaramunda,9
Palma de Mallorca
Spain
07003
jripoll@ibsalut.caib.es

Additional identifiers

Protocol serial number
PI09/90841

Study information

Scientific Title
A randomised controlled trial on the efficacy of exhaled carbon monoxide measurement plus brief physician's advice for smoking cessation

Study objectives

Smoking is the leading cause of preventable death in industrialized countries. It has long been known that the effects of tobacco on health are multiple. The tobacco causes or encourages the development of different cancers, is the major cardiovascular risk factor, the most important known cause of chronic obstructive pulmonary disease and a risk factor for many health problems. Despite this knowledge, the prevalence of smoking in our country remains high. According to the National Health Survey of 2006 in the adult population, 31.56% men and 21.51% of women are daily smokers. Of these, 79% men and 70% of women smoke 10 or more cigarettes daily.

Hypotheses:

1. The implementation of exhaled CO₂ monitoring by cooximetry for smokers in precontemplative or contemplative phase of quitting, improves the quit rate at 12 months by 5% more than brief physician's advice alone which achieves minimum quit rates of 5-7%
2. The implementation of exhaled CO₂ monitoring by cooximetry for smokers in precontemplative or contemplative phase of quitting, reduces cigarette consumption at 12 months more than brief physician's advice alone
3. The implementation of exhaled CO₂ monitoring by cooximetry for smokers in precontemplative or contemplative phase of quitting, increases the motivation to quit smoking at 12 months more than brief physician's advice alone

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ethics Committee on Human Research of the Balearic Islands approved on the 24th of September 2008 (ref: IB 985/08)

Primary study design

Interventional

Study design

Parallel randomised controlled trial with blind evaluation

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Smoking cessation

Interventions

Patients will be randomised to either

1. Control Group (CG): Brief face-to-face anti-smoking advice from the physician during patient consultation
2. Intervention Group (IG): Brief advice plus exhaled CO measure

There will be a follow-up evaluation at 6 months of inclusion and at 12 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Sustained abstinence (at 6 and 12 months) validated by urine cotinine test

Key secondary outcome(s)

1. Prevalence of smoking cessation, self reported and confirmed by both cotinine test
2. Cigarettes reduction
3. Variation in phase of the abandonment of smoking

Completion date

15/10/2012

Eligibility**Key inclusion criteria**

1. Smokers ≥ 18 years attended for any reason
2. Smokers in contemplation or precontemplation phase

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Smokers in preparation phase of quitting
2. Patients with terminal illness or in a state of health that prevents understanding of study aims and signed informed consent
3. Pregnant and/or breast-feeding women

Date of first enrolment

15/10/2010

Date of final enrolment

15/10/2012

Locations

Countries of recruitment

Spain

Study participating centre

C/Reina Esclaramunda,9

Palma de Mallorca

Spain

07003

Sponsor information

Organisation

Health Service of the Balearic Islands (Servei de Salut de les Illes Balears [IB-salut]) (Spain)

ROR

<https://ror.org/00d9y8h06>

Funder(s)

Funder type

Government

Funder Name

Health Research Fund (Fondo de Investigaciones Sanitarias [FIS]) (Spain)

Results and Publications

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?
Protocol article	protocol	04/07/2012		Yes	No