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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	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 21/07/2010	**Overall study status** Completed	
Last Edited 12/10/2012	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design
Parallel randomised controlled trial with blind evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Mr Alfonso Leiva Rus [aleiva@ibsalut.caib.es] to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
15/10/2010

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

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
942 patients

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
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Sponsor information

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

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Sponsor type
Government

ROR
https://ror.org/00d9y8h06

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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