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Periostin and periodontal disease as modifiers of atherosclerotic coronary artery disease

Submission date
24/04/2015

Recruitment status
No longer recruiting

Registration date
23/11/2015

Overall study status
Completed

Last Edited
20/12/2017

Condition category
Circulatory System

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Atherosclerosis is a serious condition where arteries become clogged up with fatty substances known as plaques. Plaques make the arteries harden and narrow, which restricts blood flow and can cause damage to organs by stopping them from working properly. They can also lead to blood clots which can trigger a stroke or heart attack. Atherosclerosis is the stage before cardiovascular disease, and it does not usually have symptoms until it is advanced and a person's blood circulation is already restricted or blocked. When it is diagnosed at this late stage it is termed cardiovascular disease. Recent studies have shown a link between complications arising from gum disease (periodontal disease) and serious conditions like atherosclerosis. There is some evidence to suggest that preventing gum disease by practicing good oral health, such as regularly brushing your teeth, may help reduce your risk of developing heart disease. Biomarkers (biological markers) are molecules that come from cells which can be found circulating in the blood. Periostin is a biomarker that has been linked to gum disease, among other conditions. The aim of this study is to see if levels of periostin in the blood of patients with atherosclerosis change after the patients receive treatment for gum disease.

Who can participate?
Adults diagnosed with atherosclerosis and gum disease.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) receive surgical dental treatment for gum disease. Those in group 2 (control group) receive non-surgical dental treatment (i.e. scaling and root planing). All participants have blood tests at baseline, then at follow-up 2 weeks, 1 month, 3 months and 6 months after treatment.

What are the possible benefits and risks of participating?
The results of this study will provide valuable information that could potentially improve treatment for atherosclerotic disease. Also, each participant in this study has free treatment of his/her periodontal disease. Furthermore, the follow-up visits are beneficial because they reinforce oral hygiene techniques.

Where is the study run from?
1. University of Granada (Spain)
2. University Hospital Virgen de las Nieves (Hospital Universitario Virgen de las Nieves) (Spain)

When is the study starting and how long is it expected to run for?
September 2014 to December 2018

Who is funding the study?
1. 7th Framework Programme, Co-funding of Regional, National, and International Programmes (COFUND) - Marie Curie Actions (Spain)
2. Government of Andalucia (Consejería Economía, Innovación, Ciencia y Empleo, Junta de Andalucia) (Spain)

Who is the main contact?
Dr M Padial-Molina

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PerioAteroma-2015

Study information

Scientific Title
Periostin and periodontal disease as modifiers of atherosclerotic coronary artery disease: a randomised controlled trial

Study objectives
Periodontal treatment improves systemic biomarkers of atherosclerotic coronary artery disease through a reduction of circulating levels of periostin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Research Ethics Committee, University of Granada, 27/01/2015, ref: 937.

Study design
Randomised open-blind controlled interventional single-centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Periodontal and atherosclerotic coronary artery disease

Interventions
1. Intervention: surgical treatment of periodontal disease by periodontal pocket reduction (modified Widman flap) and bone surgery (to smooth shallow boney craters) if required.
2. Control: no treatment (oral maintenance by non-surgical therapy (scaling and root planing).
Both groups have follow-up at 2 weeks, 1 month, 3 months and 6 months post-intervention.

Intervention Type
Procedure/Surgery

Primary outcome measure
Serum markers of atherosclerotic coronary artery disease and periostin.

Secondary outcome measures
Associated signs and markers of atherosclerosis and periodontal status.

Overall study start date
25/09/2014

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Aged 18-75
2. Diagnosed atherosclerotic coronary artery disease
3. Diagnosed chronic severe periodontal disease

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Coronary event less than 6 months before enrolment
2. Renal failure (creatinine>1.5mg/dL)
3. Uncontrolled liver or pulmonary disease
4. Malignant tumour
5. Autoimmune disease
6. Neurologic or psychiatric disorder
7. Uncontrolled diabetes mellitus (HbA1c >8)
8. Presence of infectious disease (aside from periodontal)
9. Antibiotic or periodontal therapy 3 months before start of study
10. Alcoholism or drug abuse
11. Total edentulism
12. Other ongoing oral condition (orthodontic treatment, caries, etc.)
13. Any other contraindication for treatment or unwilling or unable for any reason to provide informed consent and participate in study.

Exclusion criteria after enrolment:
1. Periodontal disease progression of more than 2mm at the 3 months re-evaluation, (re) infarction, cardiovascular (re)intervention, or death.

Date of first enrolment
01/02/2016

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
Spain

Study participating centre
University of Granada
School of Dentistry
University Campus of Cartuja (Colegio Máximo, Campus Universitario de Cartuja, S/N)
Granada
Spain
18071

Study participating centre
University Hospital Virgen de las Nieves (Hospital Universitario Virgen de las Nieves)
Av. de las Fuerzas Armadas, 2
Granada
Spain
18014

Sponsor information

Organisation
University of Granada

Sponsor details
Gran Vía nº 48 - 2º planta
Granada
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18071

Sponsor type
University/education

Website
www.ugr.es

ROR
https://ror.org/04njjy449

Funder(s)

Funder type
Research organisation

Funder Name
7th Framework Programme, Co-funding of Regional, National, and International Programmes (COFUND) - Marie Curie Actions (Spain)

Funder Name
Government of Andalucia (Consejería Economía, Innovación, Ciencia y Empleo, Junta de Andalucia) (Spain)

Results and Publications

Publication and dissemination plan
Publication in a peer-review journal, with presentation at relevant scientific/non-scientific meetings.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request