

# A Mediterranean diet for preventing heart failure and atrial fibrillation in hypertensive patients

<b>Submission date</b> 02/05/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/07/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/08/2020	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

We aim to study the effects of a Mediterranean diet, as compared with a low-fat diet, on the incidence of heart failure and atrial fibrillation (irregular heart rate) in hypertensive (high blood pressure) patients at high risk of heart disease.

### Who can participate?

Male and female patients aged between 55 and 75 with hypertension (high blood pressure), being treated with antihypertensive (blood pressure lowering) medication, and at high risk of heart disease.

### What does the study involve?

Participants will be randomly allocated into one of two groups: the control group, who will follow a low-fat diet, or the intervention group, who will follow a Mediterranean diet. Participants will come to the medical office where the following tests will be conducted: blood pressure measurements, electrocardiogram and echocardiogram, blood and urine tests, and measurement of weight, height, waist circumference and hip contour. Participants will also attend educational talks about hypertension and healthy eating. Participants will be given a booklet which will include essential information from the talks and a seasonal menu, tailored for each group.

### What are the possible benefits and risks of participating?

Participants will benefit from personalized dietary monitoring. No risk to the participants is foreseen, because they will only follow a healthy diet for hypertension and receive information about healthy living. We will not modify any participant's antihypertensive drug treatment.

### Where is the study run from?

The Al-Andalus research group, which consists of general practitioners, specialists, nurses, statisticians and a dietitian. The study will be carried out at the Ronda Historica Health Center (Spain).

When is the study starting and how long is it expected to run for?

Recruitment will start in June 2012. Participants will be enrolled on the study for a period of 12 months. Every participant will be monitored for at least two years. Consequently, the study is expected to finish at the end of 2015.

Who is funding the study?

Funding has been provided by Instituto de Salud Carlos III, Consejería de Salud - Junta de Andalucía and CIBERobn.

Who is the main contact?

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## Contact information

### Type(s)

Scientific

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

PI-0271/2010 and PI10/01690

## Study information

### Scientific Title

Efficacy of a Mediterranean diet in primary prevention of heart failure and atrial fibrillation in high risk hypertensive patients

### Acronym

ICFAMED

### Study objectives

ICFAMED - Insuficiencia Cardíaca (Heart Failure), Fibrilación Auricular (Atrial Fibrillation) and dieta MEDiterránea (MEDiterranean diet).

A Mediterranean dietary pattern versus a low-fat diet, applied to high-risk hypertensive patients who have not yet developed heart failure (HF) or atrial fibrillation (AF) reduces the incidence of both cardiac complications, improves echocardiographic parameters with prognostic value, and lowers clinic and ambulatory blood pressure.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics and Health Research Committee of Primary Care Division of Sevilla, Spain, 05 May 2010

### **Study design**

Randomized controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

### **Study type(s)**

Quality of life

### **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

### **Health condition(s) or problem(s) studied**

Cardiovascular disease (heart failure and atrial fibrillation)

### **Interventions**

Participants are randomly assigned into two equal groups:

1. Mediterranean-style diet
2. Low-fat diet according to American Heart Association guidelines

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Incidence of heart failure and/or atrial fibrillation at baseline, after 1 year of follow-up and after two years of follow-up (end of study)

## Secondary outcome measures

### 1. Ecocardiographic variables:

- 1.1. Left ventricular mass
- 1.2. Systolic function
- 1.3. Diastolic function
- 1.4. Myocardial performance index

### 2. Blood pressure variables:

- 2.1. Clinic blood pressure (BPc)
- 2.2. Ambulatory blood pressure (ABP), obtained by ambulatory blood pressure monitoring for 24 hours
- 2.3. Performance of blood pressure during sleep (dipper, non dipper, extreme dipper, raiser)
- 2.4. Ambulatory pulse pressure
- 2.5. White-coat phenomenon (differences BPc ABP > 20 mmHg for systolic and/or BPc ABP > 10 mmHg for diastolic BP)

Measured at baseline, after 1 year of follow-up and after two years of follow-up (end of study).

## Overall study start date

01/06/2012

## Completion date

01/06/2015

## Eligibility

### Key inclusion criteria

Participants are community-dwelling hypertensive patients, 55 to 75 years old, at high cardiovascular risk, with pharmacological treatment antihypertensive, without a personal documented history of cardiovascular disease (CVD): coronary heart disease, stroke, heart failure (HF) or atrial fibrillation (AF), who fulfill at least one of the two following criteria:

1. Type 2 diabetes mellitus
2. Two or more of the cardiovascular risk factors:
  - 2.1. Current smoker
  - 2.2. Lipid disorders (low density lipoprotein cholesterol [LDL-cholesterol]  $\geq$  160 mg/dl or high density lipoprotein cholesterol [HDL -cholesterol] < 40 mg/dl or treatment with hypolipidemic drugs)
  - 2.3. Obesity (body mass index  $\geq$  30 Kg/m<sup>2</sup>)
  - 2.4. Family history of premature CVD

### Participant type(s)

Patient

### Age group

Adult

### Sex

Both

### Target number of participants

n = 174 high-risk hypertensive participants

**Total final enrolment**

180

**Key exclusion criteria**

1. Previous history of cardiovascular disease (coronary heart disease, stroke, HF or AF)
2. Body mass index > 40 Kg/m<sup>2</sup>
3. Severe chronic disease with poor prognosis
4. Illegal drug use or chronic alcoholism
5. Physical limitations, mental or intellectual barriers to participate in the trial
6. Low predicted likelihood of changing dietary habits
7. Any condition that may affect the development of the trial

**Date of first enrolment**

01/06/2012

**Date of final enrolment**

01/06/2015

**Locations****Countries of recruitment**

Spain

**Study participating centre**

C/ Jerusalem, s/n

Sevilla

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41007

**Sponsor information****Organisation**

Carlos III Health Institute (Instituto de Salud Carlos III) (Spain)

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.isciii.es>

**ROR**

<https://ror.org/00ca2c886>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Carlos III Health Institute (Instituto de Salud Carlos III) (Spain) ref: PI10/01690

**Funder Name**

Ministry of Health of the Andalusian (Consejería de Salud de la Junta de Andalucía) (Spain) ref: PI0271/2010

**Funder Name**

CIBER Pathophysiology of Obesity and Nutrition (CIBER Fisiopatología de la Obesidad y Nutrición (Spain)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

2017 poster in [https://www.researchgate.net/publication/318043808\\_Effect\\_of\\_a\\_Mediterranean\\_Diet\\_on\\_the\\_Primary\\_Prevention\\_of\\_Atrial\\_Fibrillation\\_](https://www.researchgate.net/publication/318043808_Effect_of_a_Mediterranean_Diet_on_the_Primary_Prevention_of_Atrial_Fibrillation_)

2018 abstract in <https://onlinelibrary.wiley.com/doi/full/10.1111/eci.12926> (added 10/08/2020)

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration