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# The effect of an intensive intervention on life style in cardiovascular risk in an HIV-infected cohort with moderate to high cardiovascular risk

**Submission date**
20/02/2015

**Recruitment status**
No longer recruiting

**Registration date**
02/03/2015

**Overall study status**
Completed

**Last Edited**
10/05/2021

**Condition category**
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
People living with HIV seem to be at a higher risk of cardiovascular disease than the general population. Possible reasons for this include the effect of the HIV virus, effects of antiretroviral drugs and classic cardiovascular risk factors, some of them being more prevalent in HIV-infected patients. Cardiovascular events (events that result in heart damage – for example heart attacks) have become a severe health problem as they are the first cause of death and disease in most countries in the developing world. As HIV infected patients are living longer, cardiovascular risks are an emerging problem in patients treated with HAART (a customised combination of medications to treat HIV). The aim of this study is to compare how well an intensive lifestyle intervention (program) performs against a standard intervention in reducing cardiovascular risk in HIV infected patients. The influence of HAART on the metabolism of HIV patients will also be investigated.

Who can participate?
HIV infected adults (aged at least 18) with a moderate to high cardiovascular risk.

What does the study involve?
Participants are randomly allocated into one of two different groups. Those in group 1 are assigned to the control group and are given routine care and advice on lifestyle. Those in group 2 are assigned to the intervention group and are given an intensive, multidisciplinary lifestyle intervention covering diet, exercise counseling and help to give up smoking. Statistical analyses are used to compare the cardiovascular risk of both groups of people 36 weeks after the start of the study.

What are the possible benefits and risks of participating?
There are no risk for the patients to participate in the study. The benefits are related with an improvement in the control and management of cardiovascular risk factors.

Where is the study run from?
Bellvitge University Hospital (Spain)

When is the study starting and how long is it expected to run for?
June 2007 to January 2012

Who is funding the study?
Bellvitge University Hospital (Spain)

Who is the main contact?
Dr Maria Saumoy

# Contact information

### Type(s)
Scientific

### Contact name
Dr Maria Saumoy

### Contact details
Feixa Llarga s/n
Hospitalet de Llobregat
Spain
08907

# Additional identifiers

### Protocol serial number
N/A

# Study information

### Scientific Title
The effect of an intensive intervention on life style in cardiovascular risk in an HIV-infected cohort with moderate to high cardiovascular risk: a randomized trial

### Study objectives
1. An intensive lifestyle intervention may decrease cardiovascular risk in HIV infected patients with moderate to high cardiovascular risk (Framingham score > 10%).
2. Detection of subclinical carotid atherosclerosis by carotid ultrasound may improve cardiovascular risk stratification.
3. An intensive lifestyle intervention may prevent subclinical atherosclerosis progression.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Bellvitge University Hospital, 10/05/2007, ref: PR096/07

### Study design
Single center, pilot, randomized trial

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
HIV-infected patients, virologically controlled and a cardiovascular risk measured by Framingham score >10%

### Interventions
Patients were randomized 1:1 into 2 groups:
1. The intervention group, in which patients underwent an intensive, multidisciplinary lifestyle intervention by a dietitian (diet and exercise counseling) and a preventive health physician (to stop smoking)
2. Control group, in which patients continued with routine care and received advice on lifestyle

### Intervention Type
Behavioural

### Primary outcome(s)
1. Changes in the lipid parameters
2. Framingham score

Both measured at 36 months

### Key secondary outcome(s))
1. Carotid-intima media thickness
2. Cardiovascular biomarker changes

Both measured at 36 months

### Completion date
31/01/2012

## Eligibility

### Key inclusion criteria
1. Documented HIV infection
2. Age older than 18 years
3. Stable antiretroviral regimen
4. Undetectable viral load for the previous 3 months
5. Cardiovascular risk estimation based on the FS greater than 10%

### Participant type(s)
Patient

### Healthy volunteers allowed
No

**Age group**
Adult

**Lower age limit**
18 years

**Sex**
All

**Total final enrolment**
54

**Key exclusion criteria**
1. Previous cardiovascular disease
2. Diabetes mellitus
3. Microalbuminuria
4. Dyslipidemia due to hypothyroidism
5. Nephrotic syndrome or renal insufficiency (creatinine clearance< 50 mL/min)
6. Decompensated cirrhosis

**Date of first enrolment**
17/03/2008

**Date of final enrolment**
31/01/2012

# Locations

**Countries of recruitment**
Spain

**Study participating centre**
**Bellvitge University Hospital**
Feixa Llarga, s/n
L'Hospitalet de Llobregat
Barcelona
Spain
08907

# Sponsor information

**Organisation**
Bellvitge University Hospital

**ROR**

https://ror.org/00epner96

# Funder(s)

**Funder type**
Not defined

**Funder Name**
Bellvitge University Hospital (Spain)

# Results and Publications

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 01/03/2016 | 10/05/2021 | Yes | No |