

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 02/03/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/05/2021	Condition category Infections and Infestations	<input type="checkbox"/> 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
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Spain
08907

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**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 measure

1. Changes in the lipid parameters
2. Framingham score

Both measured at 36 months

Secondary outcome measures

1. Carotid-intima media thickness
2. Cardiovascular biomarker changes

Both measured at 36 months

Overall study start date

15/06/2007

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

54 participants

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

Sponsor details

c/o Daniel Podzamczar
Feixa Llarga s/n
Hospitalet de Llobregat
Spain
08907

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00epner96>

Funder(s)

Funder type

Not defined

Funder Name

Bellvitge University Hospital (Spain)

Results and Publications

Publication and dissemination plan

We are writing a paper with the results.

Intention to publish date

28/02/2015

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