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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
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Spain
08907

Additional identifiers

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

Primary study design
Interventional

Study design
Single center, pilot, randomized trial

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