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# Switching from efavirenz/tenofovir /emtricitabine (TDF/FTC/EFV) to abacavir /lamivudine/maraviroc (ABC/3TC/MVC) to assess antiretroviral activity in cerebrospinal fluid

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 02/02/2011 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 18/04/2011 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 21/01/2019 | Infections and Infestations | |

**Plain English summary of protocol**

Background and study aims

Despite a sharp decrease in human immunodeficiency virus (HIV)-associated dementia with the use of combined antiretroviral drugs, there is a high prevalence of mild or moderate neurocognitive disorders in patients receiving antiretroviral treatment. A low level viral activity may persist in the central nervous system even in those patients presenting undetectable viral load, leading to local inflammation, neuronal damage and neurocognitive impairment. The aim of this study is to find out whether switching from a first-line antiretroviral treatment to a combination with a higher penetration to the central nervous system could reduce inflammation and neurocognitive impairment

Who can participate?

HIV-positive adults aged over 18 on efavirenz/tenofovir/emtricitabine treatment for at least 24 weeks, undetectable HIV viral load in the last 24 weeks, and neurocognitive impairment.

What does the study involve?

Patients will be switched from emtricitabine/tenofovir/efavirenz once daily to lamivudine /abacavir once daily and maraviroc twice daily. A neuropsychological test will be performed at weeks 0 and 48, and a lumbar puncture at weeks 0 and 24. Every patient will continue with routine visits every 3 - 4 months.

What are the possible benefits and risks of participating?

The use of a combination treatment with better penetration into the brain could reduce neuronal damage and inflammation and improve neurocognitive impairment. Risks of taking part include the side effects associated with the new medications.

Where is the study run from?
Institute of Biomedical Investigations of Bellvitge (Spain).

When is the study starting and how long is it expected to run for?
The study ran from January 2011 to July 2013.

Who is funding the study?
ViiV Healthcare (UK).

Who is the main contact?
Dr Daniel Podzamczer

# Contact information

### Type(s)
Scientific

### Contact name
Dr Daniel Podzamczer

### Contact details
c/Feixa Llarga s/n. L'Hospitalet
Barcelona
Spain
08907

# Additional identifiers

### Clinical Trials Information System (CTIS)
2010-022202-41

# Study information

### Scientific Title
Switching from efavirenz/tenofovir/emtricitabine (TDF/FTC/EFV) to abacavir/lamivudine /maraviroc (ABC/3TC/MVC) to assess antiretroviral activity in cerebrospinal fluid: a prospective one-arm pilot study

### Acronym
MRVstudy-10 (XUMAKER)

### Study objectives
Change to a regimen with greater cerebrospinal fluid (CSF) penetration will be associated with a lower CSF viral load, a decrease in inflammatory markers and possibly with an improvement in neurocognitive tests.

On 19/06/2014 the following changes were made to the trial record:
1. The public title was changed from 'Switching from efavirenz/tenofovir/emtricitabine (TDF/FTC /EFV) to abacavir/lamivudine/nevirapine (ABC/3TC/NVP) to assess antiretroviral activity in cerebrospinal fluid' to 'Switching from efavirenz/tenofovir/emtricitabine (TDF/FTC/EFV) to

abacavir/lamivudine/maraviroc (ABC/3TC/MVC) to assess antiretroviral activity in cerebrospinal fluid'
2. The scientific title was changed from 'Switching from efavirenz/tenofovir/emtricitabine (TDF/FTC/EFV) to abacavir/lamivudine/nevirapine (ABC/3TC/NVP) to assess antiretroviral activity in cerebrospinal fluid: a prospective one arm pilot study' to 'Switching from efavirenz/tenofovir/emtricitabine (TDF/FTC/EFV) to abacavir/lamivudine/maraviroc (ABC/3TC/MVC) to assess antiretroviral activity in cerebrospinal fluid: a prospective one-arm pilot study'
3. The anticipated end date was changed from 01/04/2012 to 01/07/2013

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
University Hospital of Bellvitge, Barcleona [CEIC Hospital Universitari de Bellvitge, Barcelona] (Spain), 07/10/2010

## Primary study design
Interventional

## Study design
Prospective one-arm pilot study

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Human immunodeficiency virus (HIV)

## Interventions
Current interventions as of 19/06/2014:
1. This is a single-arm study. Patients presenting confirmed neurocognitive impairment, with documented CCR5+ viral tropism, will be switched from emtricitabine 200 mg/tenofovir 245 mg/efavirenz 600 mg once daily (OD) to lamivudine 300 mg/abacavir 600 mg OD and maraviroc 300 mg twice daily (BID)
2. A neuropsychological test will be performed at weeks 0 and 48, and a lumbar puncture at weeks 0 and 24
3. Every patient will continue with routine visits every 3 - 4 months

Previous interventions:
1. This is a single-arm study; all diagnosed of neuropsychological impairment, CCR5+ patients will be switched from emtricitabine 200 mg/tenofovir 245 mg/efavirenz 600 mg four times daily (QD) to lamivudine 300 mg/abacavir 600 mg QD and maraviroc 300 mg twice daily (BID).
2. A neuropsychological test will be performed at weeks 0, 24 and 48, and a lumbar puncture at weeks 0 and 48
3. Every patient will continue his/her routine control every 3 - 4 months

## Intervention Type
Drug

## Phase
Phase IV

### Drug/device/biological/vaccine name(s)
Current drugs as of 19/06/2014: 1. Efavirenz/tenofovir/emtricitabine (TDF/FTC/EFV) 2. Abacavir /lamivudine/maraviroc (ABC/3TC/MVC) Previous drugs: 1. Efavirenz/tenofovir/emtricitabine (TDF /FTC/EFV) 2. Abacavir/lamivudine/nevirapine (ABC/3TC/NVP)

### Primary outcome(s)
Viral load (VL) less than 5 copies/ml in CSF, evaluated at week 48

### Key secondary outcome(s)
Evaluated at week 48:
1. Viral load (VL) less than 50 copies/ml in CSF
2. Central nervous system (CNS) inflammatory markers change in CSF
3. Neurocognitive tests

### Completion date
01/07/2013

## Eligibility

### Key inclusion criteria
1. Human immunodeficiency virus positive (HIV+)
2. Adults aged over 18 years
3. HLA-B*57:01:01 negative
4. On TDF/FTC/EFV treatment for at least 24 weeks and undetectable HIV viral load in the last 24 weeks
5. Neurocognitive impairment
6. CCR5+ (pro-viral deoxyribonucleic acid [DNA])
7. Signed informed consent

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### Key exclusion criteria
1. Alanine aminotransferase (ALT) greater than 5 fold upper normal limit
2. Renal impairment (creatinine clearance [Cl cr] less than 50 ml/min)
3. Haemoglobin less than 9 g/dl
4. Neutropenia (PMN) less than 1000/ml
5. Platelets less than 30,000/mm3

6. Opportunistic infection, cancer and /or any disease which could alter blood brain barrier permeability (meningitis, cancer, etc.)
7. Neuro-psychiatric disease (previous or current)
8. Illicit drugs use

### Date of first enrolment
27/01/2011

### Date of final enrolment
01/07/2013

## Locations

### Countries of recruitment
Spain

### Study participating centre
**c/Feixa Llarga s/n. L'Hospitalet**
Barcelona
Spain
08907

## Sponsor information

### Organisation
Institute of Biomedical Investigations of Bellvitge [Institut d'Investigació Biomèdica de Bellvitge (IDIBELL)] (Spain)

### ROR
https://ror.org/0008xqs48

## Funder(s)

### Funder type
Industry

### Funder Name
ViiV Healthcare (UK)

## Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/07/2015 | 21/01/2019 | Yes | No |