

# Efficacy and safety of daily supplementation with PMG151 in individuals living with Human Immunodeficiency Virus (HIV)

<b>Submission date</b> 20/08/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 15/09/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 14/12/2010	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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Ouagadougou  
Burkina Faso  
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## Additional identifiers

### Protocol serial number

EC2008/06/PMG151/01

## Study information

### Scientific Title

Tolerance, Physical and immunological response in Human Immunodeficiency Virus (HIV) seropositive persons supplemented daily with PMG151: Double blind, randomised controlled clinical trial

**Acronym**

PMG151

**Study objectives**

Daily supplementation with PMG151 in HIV seropositive persons has no side effects at long term and improve their physical conditions and immunological response.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The local ethics committee (Comite d'Ethique pour la Recherche en Sante [CERS]) in Burkina Faso approved on the 1st of April 2009

**Study design**

Double blind randomised placebo controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

AIDS/HIV

**Interventions**

Group 1: ART Treatment-experienced individuals: In this group 78 subjects will be treated with active form of PMG151 and 78 subjects with Placebo

Group 2: ART Treatment-naïve individuals: In this group 48 subjects will be treated with active form of PMG151 and 48 subjects with placebo.

Dose regimen: 2 capsules of PMG151/placebo (330mg each capsules) two times daily for 12 months. Capsules were taken orally with water.

The follow up period for each included participant is 12 months.

The study was a double blind study and assignment of study participant to take active form or placebo is randomised. The list of randomisation numbers was generated by a computer.

Placebo used was maize starch.

**Intervention Type**

Other

**Phase**

Phase IV

**Primary outcome(s)**

Tolerance, safety during supplementation period:

Medical examination for adverse event at each monthly visit, blood taken at baseline, 3, 6, 9 and 12 months for haematology (complete blood count [CBC]) and blood chemistry

**Key secondary outcome(s))**

Establish effects of supplementation on:

1. Nutritional status of patients (weight, brachial perimeter...)
2. Viral load
3. CD4 and CD8 counts

**Completion date**

04/04/2011

## Eligibility

**Key inclusion criteria**

1. HIV1 seropositive persons
2. Age between 18-55 years
3. Written informed consent given
4. Live in the study area for 12 next months

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

55 years

**Sex**

All

**Key exclusion criteria**

1. Pregnant and/or lactating females
2. HIV2 seropositive or HIV1 and HIV2 coinfection
3. High blood pressure (Hypertension)
4. Cardiac or renal disease
5. History of known sickle cell disease
6. Alcohol abuse

**Date of first enrolment**

14/09/2009

**Date of final enrolment**

04/04/2011

## Locations

## Countries of recruitment

Burkina Faso

## Study participating centre

University Hospital Yalgado Ouedraogo

Ouagadougou

Burkina Faso

03 POB 7022

## Sponsor information

### Organisation

Centre for Traditional Medicine and Integrated Care (Centre de Medecine Traditionelle et de Soins integrés [CMTSI]) (Burkina Fas

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Centre for Traditional Medicine and Integrated Care (Centre de Medecine Traditionelle et de Soins integrés [CMTSI]) (Burkina Faso)

### Funder Name

Ministry of Health (Burkina Faso) - General Directorate of Medicines Pharmacy and Laboratories (Direction Generale de la Pharmacie du Medicament et des Laboratoires [DGPML])

## 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?
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