ISRCTN22931534 https://doi.org/10.1186/ISRCTN22931534

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

Submission date 20/08/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 15/09/2010	**Overall study status** Completed	
Last Edited 14/12/2010	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet [In French]

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 measure
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

Secondary outcome measures
Establish effects of supplementation on:
1. Nutritional status of patients (weight, brachial perimeter...)
2. Viral load
3. CD4 and CD8 counts

Overall study start date
14/09/2009

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants

252 subjects planned: 156 treatment-experienced and 96 treatment-naïve individuals. Actually 156 treatment-experienced and 30 treatment-naïve (Recruitment closed)

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

Sponsor details
General Directorate of Medicines Pharmacy and Laboratories
(Direction Generale de la Pharmacie du Medicament et des Laboratoires [DGPML])
Ouagadougou
Burkina Faso
03 POB 7009

Sponsor type
Hospital/treatment centre

Website

http://www.dgpml.sante.gov.bf

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration