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Effects of V.II-BE on the number of circulating virus particles and immune cells in the blood in patients diagnosed positive with HIV

Submission date
27/09/2012

Recruitment status
No longer recruiting

Registration date
08/10/2012

Overall study status
Completed

Last Edited
06/06/2014

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
We were carrying out this study in order to measure the effect of an herbal preparation containing a special extract of the medicinal plants chamomile, rose, lavender, myrrh, willow bark and spiny rush on HIV infection. The aim is to test the potential of the herbal preparation for an improvement in virus load and immune cells in patients diagnosed as HIV positive but not yet eligible for treatment with antiviral medications. This situation, where the patient cannot receive medication because the risk of adverse effects and formation of resistance, can be considered a therapeutic gap, leaving the patient on his/her own with a dreadful perspective. A well-tolerated herbal preparation contributing to controlling the virus load and the immune status in the early stages of an HIV infection is expected to increase the quality of life of the patients, and delay the aggravation of the response of the immune system even to minor threats.

Who can participate?
Adults up to the age of 50 diagnosed with HIV who have a virus load and CD4-cell count below the threshold for the prescription of an antiviral medical treatment.

What does the study involve?
Within the study, only routine examination results are documented, as they would have been obtained from regular medical supervision. In addition, the typical laboratory blood examinations on liver and kidney function and blood lipids are documented as an additional safety aspect. The study is designed for an observation period of 3 months.

What are the possible benefits and risks of participating?
A delay of the requirement of antiviral treatment is a major clinical achievement in HIV treatment: it increases the quality of life of HIV patients, and postpones the risk of resistance formation against antiviral medications, as well as the risk of adverse effects. In previous examinations and experience with exposure to the herbal preparation, no adverse reactions have been observed. Participating patients are screened for potential adverse events.

Where is the study run from?
The study is run from clinical HIV healthcare centres.

When is the study starting and how long is it expected to run for?
The study started in 2012 and is expected to finish in the same year.

Who is funding the study?
Funding has been provided by GHS AG in Liechtenstein, a company financially supporting the development of the herbal preparation by its inventor, Mrs Monica Volkmar.

Who is the main contact?
Dr Mathias Schmidt
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GHS-0312/kl

Study information

Scientific Title
Documentation of the clinical effect and safety of V.II-BE on immunological parameters of HIV-infected patients: an open prospective trial

Study objectives

The intake of the herbal preparation V.II-BE contributes to lowering the virus load and increases the number of circulating CD4 cells in patients infected with human immunodeficiency virus (HIV), but still not sufficiently diseased to be eligible for treatment with antiviral medication.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the study centre in Cluj, Romania, 28/05/2012

Study design
Open prospective study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
HIV at a stage where antiviral treatment is not yet recommended according to medical guidelines

Interventions
All patients receive the V.II-BE solution (special extract of the medicinal plants chamomile, rose, lavender, myrrh, willow bark and spiny rush). The product contains 90% ethanol. The recommended dose is 60 drops twice daily with a little water for 3 months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
V.II-BE (herbal preparation)

Primary outcome measure
Virus load and CD4 cell count

Secondary outcome measures
Safety laboratory values

Overall study start date
01/06/2012

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Patients up to the age of 50 diagnosed with an HIV infection
2. Virus load below 50,000 copies/ml of blood
3. CD4 cell count above 350 cells/µl of blood
4. Stable virus load for the past 6 months

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30-40

Key exclusion criteria
Patients cannot be included if:
1. They receive antiviral medication
2. They are treated with antibiotics
3. They undergo chemotherapy for cancer treatment
4. They have a background of abusing alcohol or illicit drugs
5. They have a co-infection with hepatitis
6. They are, in the case of women, pregnant or lactating

Date of first enrolment
01/06/2012

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Austria

Romania

Study participating centre
Dorotheergasse 7
Wien
Austria
1010

Sponsor information

Organisation
GHS AG (Liechtenstein)

Sponsor details
Letzanaweg 23
POB 20
Triesen
Liechtenstein
FL-9495

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
GHS AG (Liechtenstein)

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