

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

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| Submission date 27/09/2012 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 08/10/2012 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 06/06/2014 | Condition category Infections and Infestations | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> 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?

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Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Study type(s)

Screening

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(s)

Virus load and CD4 cell count

Key secondary outcome(s)

Safety laboratory values

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/ μ l of blood
4. Stable virus load for the past 6 months

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

Funder(s)

Funder type

Industry

Funder Name

GHS AG (Liechtenstein)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration