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(54) Title: HERBAL COMPOSITION FOR THE PROPHYLAXIS AND TREATMENT OF AIDS

(57) Abstract

A therapeutic composition for the prophylaxis and treatment of AIDS comprising a mixture of nontoxic herbs of well recognised medicinal properties. The herbal composition consists of Stephania venosa Spreng (40–60 mg), Stephania suberosa Forman (40–60 mg), Stephania glabra Roxb. Miers. (40–60 mg), Hedychium coronarium Roem (40–60 mg), Zingiber Officinalis Roscoe (30–50 mg) and Curcurma Amada (30–50 mg). The process of making the composition requires the herbs to be washed, cut into small pieces, dried and separated from all extraneous material. Each herb is then weighed according to predetermined proportions and pulverised together into a powder of about 40–100 mesh, and dried again. The herbal composition can then be filled into hard gelatin capsules. It has been found that the herbal composition improves the physical condition of AIDS patients and can alleviate or cease the symptoms of most opportunistic infections.

Herbal Composition for the Prophylaxis and Treatment of AIDS

The present invention is in the fields of medicine and pharmacology. In particular the present invention relates to herbal composition for the prophylaxis and treatment of human immunodeficiency virus (HIV) disease and Acquired Immune Deficiency Syndrome (AIDS) and AIDS related complex.

TECHNICAL FIELD

Acquired Immune Deficiency Syndrome (AIDS) is a pandemic immunosuppressive disease which results in life threatening opportunistic infection and malignancies. The disease kills the helper cells of the immune system which play a crucial role in cell mediated immunity. The progressive loss of the helper cells in the blood leads to a stage where the body is rendered incapable of resisting many bacterial, viral and parasitical invasions resulting in the AIDS patient dying from opportunistic infections. A retrovirus, designated human immunodeficiency virus (HIV-1), has been isolated and identified as the etiologic agent of this disease.

It was estimated that there were about 23 millions HIV infected patients all over the world in 1997. Of these patients, 90% live in developing countries with Asia having the highest numbers of newly infected patients.

Several agents have been reported to inhibit the growth of the human immunodeficiency virus. These include nucleoside analog reverse Transcriptase inhibitors (NRTIs) e.g. zidovudine, lamivudine, d4T (trade names) and protease inhibitors e.g. indinavir, ritonavir, nelfinavir (trade names). A combination of drugs may be used, for example 3 drug regimens that usually include 2 nucleoside analog reverse transcriptase inhibitors and a protease inhibitor, but they are complex and costly. Furthermore these compounds appear to be too toxic for prolonged use or only have a limited capability of minimising or eliminating HIV infections from the human host.

Accordingly the currently known anti-HIV drugs now available are costly and potentially toxic and inaccessible to the majority of HIV infected patients in

developing countries. Therefore all patients need less expensive, less toxic and effective anti-HIV drugs.

Herbal preparations/ treatments and medicines have been used for the treatment of various diseases in Thailand and South East Asia for several hundred years. Recent interest in natural treatment for health problems has resulted in herbal drugs being researched as to their chemical constituents, toxicity and activities.

The object of the present invention is to provide a herbal composition for the prophylaxis and treatment of AIDS and/or a method for the prophylaxis and treatment of AIDS patients using that herbal composition.

By the terms HIV and AIDS related virus is meant the commonly designated HIV series (human immunodeficiency virus) formerly called HTLV, LAV and ARV, and species thereof.

DISCLOSURE OF THE INVENTION

In one form of this invention there is proposed a method for the prophylaxis and treatment of AIDS and AIDS related complex comprising the step of administering to an animal or person a therapeutically effective amount of a preparation including an extract of one or more of the following plants; Stephania venosa Spreng, Stephania suberosa Forman, Stephania glabra Roxb. Miers., Hedychium coronarium Roem, Zingiber officinalis Roscoe and Curcurma Amada.

In a further form of the invention there is proposed a composition for the prophylaxis and treatment of AIDS and AIDS related complex including an extract of one or more of the following plants; Stephania venosa Spreng, Stephania suberosa Forman, Stephania glabra Roxb. Miers., Hedychium coronarium Roem, Zingiber officinalis Roscoe and Curcurma Amada.

In a further form of the invention there is proposed a method of inhibiting in vitro HIV infection in human T lymphocyte cells and mononuclear phagocytic lineage cells infected with HIV with a preparation consisting essentially of an extract from one or more of at least Stephania venosa Spreng, Stephania

suberosa Forman, Stephania glabra Roxb. Miers., Hedychium coronarium Roem, Zingiber officinalis Roscoe and Curcurma Amada.

In a yet further form of the invention there is proposed a composition for the prophylaxis and treatment of AIDS and AIDS related complex comprising a therapeutically acceptable composition of herbs comprising 18.0 to 19.0% of the total weight of the following formulated by weight of each of Stephania venosa Spreng, Hedychium coronarium Roem, 16.0 to 17.0% by weight of each of Stephania suberosa Forman, Stephania glabra Roxb. Miers and 14.5 to 15.5% by weight of each of Zingiber officinalis Roscoe, Curcurma Amada.

In a yet still further form of the invention there is proposed a composition for the prophylaxis and treatment of AIDS and AIDS related complex comprising each of the following of selected dried plant material in the proportions selected hereafter:

Name of herb	Classification	Weight (mg) minimum
Stephania venosa Spreng	(MENISPERMACEAE)	40
Stephania suberosa Forman	(MENISPERMACEAE)	40
Stephania glabra Roxb. Miers.	(MENISPERMACEAE)	40
Hedychium coronarium Roem	(ZINGIBERACEAE)	40
Zingiber officinalis Roscoe	(ZINGIBERACEAE)	30
Curcurma Amada	(ZINGIBERACEAE)	30

It is to be understood though that the particular weight of each plant may depending on the potency of each plant.

In a further still form of the invention there is proposed a composition for the prophylaxis and treatment of AIDS and AIDS related complex comprising the following, as dried plant materials :

Name of herb	Classification	Weight (mg)
Stephania venosa Spreng	(MENISPERMACEAE)	55
Stephania suberosa Forman	(MENISPERMACEAE)	50
Stephania glabra Roxb. Miers.	(MENISPERMACEAE)	50

Hedychium coronarium Roem	(ZINGIBERACEAE)	55
Zingiber officinalis Roscoe	(ZINGIBERACEAE)	45
Curcurma Amada	(ZINGIBERACEAE)	45

In preference the composition is in the form of a capsule, said capsule being preferentially a gelatin capsule.

In preference the composition is in the form of a liquid mixed with a syrup.

In a still further form of the invention there is proposed a process for preparing a composition for the prophylaxis and treatment of AIDS and AIDS related complex including:

(a) pulverising into powder the following amounts of dried plant material consisting essentially of:

Name of herb	Classification	Weight(mg) range
Stephania venosa Spreng	(MENISPERMACEAE)	40-60
Stephania suberosa Forman	(MENISPERMACEAE)	40-60
Stephania glabra Roxb. Miers.	(MENISPERMACEAE)	40-60
Hedychium coronarium Roem	(ZINGIBERACEAE)	40-60
Zingiber officinalis Roscoe	(ZINGIBERACEAE)	30-50
Curcurma Amada	(ZINGIBERACEAE)	30-50

(b) preparing a pharmaceutical formulation comprising the powder of step (a)

In preference the total weight of the composition of Stephania venosa Spreng, Stephania suberosa Forman, Stephania glabra Roxb. Miers., Hedychium coronarium Roem, Zingiber officinalis Roscoe and Curcurma Amada is no more than 300 mgs.

In preference the method includes giving the composition in the quantities stated twice a day before meals to a patient (human adult) who weighs 60 kg or less.

In preference the method includes giving the composition three times a day before meals to a patient (human adult) who weighs 60-100 kg.

BEST MODE OF THE INVENTION

The following detailed description and procedures are provided to illustrate the principles of the invention. They are not, however, intended to limit this invention.

After a significant period of trial and modification a mixture of the following herbs was found to be successful for treating AIDS patients.

Name of Herb	Classification
Stephania venosa Spreng	(MENISPERMACEAE)
Stephania suberosa Forman	(MENISPERMACEAE)
Stephania glabra Roxb. Miers.	(MENISPERMACEAE)
Hedychium coronarium Roem	(ZINGIBERACEAE)
Zingiber officinalis Roscoe	(ZINGIBERACEAE)
Curcurma Amada	(ZINGIBERACEAE)

Each herb was collected fresh, was washed with water, cut into small pieces, dried and separated from all extraneous material. Each herb was weighed according to predetermined proportions and pulverised together into a powder of about 40-100 mesh, and dried again. However, it is to be understood that the extracts from each subject herb can be used and prepared by known organic extraction procedures.

The resulting herbal powder composition is then filled into hard gelatin capsules. The combination of the herbal composition with an appropriate solid carrier, such as lactose, starch, and lubricants (e.g. magnesium stearate, calcium stearate) or the like can be used. Each capsule contained approximately 300 mg of the herbal powder composition.

The dosage for oral use chosen for trials is one capsule, twice a day before meals for a patient who weighs 60 kg or lower, and for a patient who weighs 60 to 100 kg, one capsule is administered three times a day before meals.

From experiments conducted so far, a therapeutically effective quantify of the referred to composition for an average human adult is at least as follows

Name of herb	Classification	Min wt (mg)
Stephania venosa Spreng	(MENISPERMACEAE)	40
Stephania suberosa Forman	(MENISPERMACEAE)	40
Stephania glabra Roxb. Miers.	(MENISPERMACEAE)	40
Hedychium coronarium Roem	(ZINGIBERACEAE)	40
Zingiber officinalis Roscoe	(ZINGIBERACEAE)	30
Curcurma Amada	(ZINGIBERACEAE)	30

It has also been found that the above minimum weights can be increased by some 20 mg for each herb.

In a first example the composition comprises the following

Name of herb	Classification	Weight (mg)
Stephania venosa Spreng	(MENISPERMACEAE)	55
Stephania suberosa Forman	(MENISPERMACEAE)	50
Stephania glabra Roxb. Miers.	(MENISPERMACEAE)	50
Hedychium coronarium Roem	(ZINGIBERACEAE)	55
Zingiber officinalis Roscoe	(ZINGIBERACEAE)	45
Curcurma Amada	(ZINGIBERACEAE)	45
	Total	300

Over one hundred patients with confirmed cases of full blown AIDS or HIV infected were treated with the composition of this invention in AIDS treatment hospitals. Both before treatment and periodically after treatment all patients were tested for the following :

hemoglobin (Hb)
white blood cells (WBC)
platelet (Plt)
polymorphonuclear (PMN)
basophol (Bas)
lymphocyte (Lymph)
monocyte (Mono)

CD4, CD8, CD4/CD8 ratio

as well as other physical conditions. It was found that most of the patients showed improved physical conditions and the symptoms of most opportunistic infections either reduced or significantly disappeared. Thus, approximately equal quantities of the herbs in the composition were found to give a therapeutic advantage.

CLAIMS

1. A method for the prophylaxis and treatment of AIDS and AIDS related complex comprising the step of administering to an animal or a person a therapeutically effective amount of an extract of one or more of the following plants; Stephania venosa Spreng, Stephania suberosa Forman, Stephania glabra Roxb. Miers., Hedychium coronarium Roem, Zingiber officinalis Roscoe and Curcurma Amada.

2. A method of inhibiting in vitro HIV infection in human T lymphocyte cells and mononuclear phagocytic lineage cells infected with HIV with a preparation consisting essentially of an extract from one or more of the following plants; Stephania venosa Spreng, Stephania suberosa Forman, Stephania glabra Roxb. Miers., Hedychium coronarium Roem, Zingiber officinalis Roscoe and Curcurma Amada.

3. A composition for the prophylaxis and treatment of AIDS and AIDS related complex including an extract of one or more of the following plants; Stephania venosa Spreng, Stephania suberosa Forman, Stephania glabra Roxb. Miers., Hedychium coronarium Roem, Zingiber officinalis Roscoe and Curcurma Amada.

4. A composition for the prophylaxis and treatment of AIDS and AIDS related complex comprising a therapeutically acceptable composition of herbs comprising 18.0 to 19.0% of the total weight of the following formulated by weight of each of Stephania venosa Spreng, Hedychium coronarium Roem, 16.0 to 17.0% by weight of each of Stephania suberosa Forman, Stephania glabra Roxb. Miers and 14.5 to 15.5% by weight of each of Zingiber officinalis Roscoe, Curcurma Amada.

5. A composition for the prophylaxis and treatment of AIDS and AIDS related complex comprising each of the following of selected dried plant material in the proportions selected hereafter:

Name of herb	Classification	Weight (mg) minimum



Stephania venosa Spreng	(MENISPERMACEAE)	40
Stephania suberosa Forman	(MENISPERMACEAE)	40
Stephania glabra Roxb. Miers.	(MENISPERMACEAE)	40
Hedychium coronarium Roem	(ZINGIBERACEAE)	40
Zingiber officinalis Roscoe	(ZINGIBERACEAE)	30
Curcurma Amada	(ZINGIBERACEAE)	30

6. A composition for the prophylaxis and treatment of AIDS and AIDS related complex comprising the following, as dried plant materials :

Name of herb	Classification	Weight (mg)
Stephania venosa Spreng	(MENISPERMACEAE)	55
Stephania suberosa Forman	(MENISPERMACEAE)	50
Stephania glabra Roxb. Miers.	(MENISPERMACEAE)	50
Hedychium coronarium Roem	(ZINGIBERACEAE)	55
Zingiber officinalis Roscoe	(ZINGIBERACEAE)	45
Curcurma Amada	(ZINGIBERACEAE)	45

7. A composition as claimed in any one of claims 3 to 6 being substantially in the form of a capsule.

8. A composition as in claim 7 wherein said capsule is a gelatin capsule.

9. A composition as claimed in any one of claims 3 to 6 wherein said composition is in the form of a liquid mixed with a syrup.

10. A composition as in any one of claims 3 to 9 wherein the total combined weight of the extracts of Stephania venosa Spreng, Stephania suberosa Forman, Stephania glabra Roxb. Miers., Hedychium coronarium Roem, Zingiber officinalis Roscoe and Curcurma Amada is no more than 300 mgs.

11. A method of prophylaxis and treatment of AIDS and AIDS related complex including administering a composition as claimed in any one of claims 3 to 10 twice a day before meals to a patient (human adult) who weighs 60 kg or less.



12. A method of prophylaxis and treatment of AIDS and AIDS related complex including administering a composition as claimed in any one of claims 3 to 10 three times a day before meals to a patient (human adult) who weighs 60-100 kg.

13. A process for preparing a composition for the prophylaxis and treatment of AIDS and AIDS related complex including:

(a) pulverising into powder the following amounts of dried plant material consisting essentially of:

Name of herb	Classification	Weight(mg) range
Stephania venosa Spreng	(MENISPERMACEAE)	40-60
Stephania suberosa Forman	(MENISPERMACEAE)	40-60
Stephania glabra Roxb. Miers.	(MENISPERMACEAE)	40-60
Hedychium coronarium Roem	(ZINGIBERACEAE)	40-60
Zingiber officinalis Roscoe	(ZINGIBERACEAE)	30-50
Curcurma Amada	(ZINGIBERACEAE)	30-50

(b) preparing a pharmaceutical formulation comprising the powder of step (a).