Journal of Clinical Trials & Research
JCTR, 3(2): 185-190
www.scitcentral.com

ISSN: 2637-7373

Original Research Article: Open Access

A Nano Botanical Composition for Treatment of Cancer

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Received May 29, 2020; Accepted June 04, 2020; Published June 28, 2020

ABSTRACT

The present patent-pending invention relates to a nano pharmaceutical immunity enhancer composition for treatment of cancer. The composition for treating cancer, preferably formed of nano herbal extracts, contains Aloe Vera, Shiitake Mushroom, Agaricus Mushroom, Reishi Mushroom, Vinca Rosea, Graviola Leaf, Camel Milk powder, Wormwood and Black Seed or extracts of them. In particular the composition is given to all types of cancer to increase immunity and to enhance the treatment of cancer. Observed results showed excellent results in 25 years for all types of cancer with no adverse or side effects.

Background of the invention: According to World Health Organization (WHO) in a report issued in 2018 [1]:

- Cancer is the second leading cause of death globally, and is responsible for an estimated 9.6 million deaths in 2018. Globally, about 1 in 6 deaths is due to cancer.
- Cancer has or will soon become the number one killer in many parts of the world.
- Tobacco use is the most important risk factor for cancer and is responsible for approximately 22% of cancer deaths.

Cancer is generally time-consuming for patients because of the need to consistently obtain reliable diagnostic information, follow prescribed therapy and manage lifestyle on a daily basis. Diagnostic information is typically obtained from a blood sample with CT SCAN, BONE SCAN, MRI, PET SCAN and Biopsy testing.

Patients with cancer may be treated by one of the following methods or by a combination of more than method depending on the case status:

Cancer treatment options include:

- Surgery: The goal of surgery is to remove the cancer or as much of the cancer as possible.
- Chemotherapy: Chemotherapy uses drugs to kill cancer cells.
- Radiation therapy: Radiation therapy uses high-powered energy beams, such as X-rays or protons, to kill cancer cells.
- Bone marrow transplant: Bone marrow is the material inside the bones that makes blood cells from blood stem cells. A bone marrow transplant allows doctor to use higher doses of chemotherapy to treat your cancer. It may also be used to replace diseased bone marrow.
- Immunotherapy: Immunotherapy, also known as biological therapy, uses the body's immune system to fight cancer.
- Hormone therapy: Some types of cancer are fueled by your body's hormones. Examples include breast cancer and prostate cancer. Removing those hormones from the body or blocking their effects may cause the cancer cells to stop growing.
- Targeted drug therapy: Targeted drug treatment focuses on specific abnormalities within cancer cells that allow them to survive.
- Cryoablation or Cryosurgery: This treatment kills cancer cells with cold probe using liquid nitrogen. A gas is pumped into the cryoprobe in order to freeze and kill the cancer tissue.
- Radiofrequency ablation: This treatment uses electrical energy to heat cancer cells, causing them to die.
- High Intensity Focused Ultrasound (HIFU): This treatment uses highly focused ultrasound waves

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Citation: Mansour A & Mansour A. (2020) A Nano Botanical Composition for Treatment of Cancer. J Clin Trials Res, 3(2): 185-190.

guided by an MRI monitor towards tumor cells and kill them when waves propagated and produce heat.

- Cyber knife: This treatment is one of the most advanced forms of radiosurgery is a painless, non-invasive treatment that delivers high doses of precisely targeted radiation.

This can be very time-consuming for patients.

Moreover, side effects of the most common treatment methods of chemotherapy and radiotherapy such as: Fatigue, Hair loss, Easy bruising and bleeding, Infection, Anemia, Nausea and vomiting, Appetite changes, constipation. Mouth, tongue, throat problems such as sores and pain with swallowing, Nerve and muscle problems such as numbness, and pain, Skin and nail changes, Urine, bladder and kidney problems, Weight loss, brain concentration and focus problems, Mood changes, changes in libido and sexual function, and fertility problems. Some chemotherapy drugs cause other types of cancer.

Bad and bitter experience of chemotherapy and radiotherapy and painful side effects lead us to formulate a safe and effective natural alternative 25 years ago which we called MG20; which stands for Mansour (author's name) and Ginin (author's town in Palestine).

Using compositions including immunity enhancer extracts; such as aloe vera, shiitake mushroom, agaricus mushroom, reishi mushroom, vinca rose, graviola leaf, camel milk powder, wormwood and black seed. It relates to the field of therapeutic natural products, particularly to plant extracts effective in treating and preventing cancer and /or conditions associated there with.

OBJECTS OF THE INVENTION

Primary object of the present invention is to provide a composition to enhance immunity. Another object of the present invention is to provide a process for the preparation of the herbal composition for treating all types of cancer.

SUMMARY OF THE INVENTION

The present invention relates to an oral pharmaceutical composition for treatment of cancer. The composition for treating cancer, preferably formed of Aloe Vera, Shiitake Mushroom, Agaricus Mushroom, Reishi Mushroom, Vinca Rosea, Graviola Leaf, Camel Milk powder, Wormwood and Black Seed or extract of them.

DETAILED DESCRIPTION OF THE INVENTION

Present invention relates to the use of a composition which can be formed as an efficient tool to enhance immunity and treat all types of cancer.

The composition is formed of the following:

Aloe vera extract

In 2010, El-Shemy et al. [2] performed a study on three extracts of aloevera leaf to evaluate the potential anticancer properties and modulatory effect of them on antioxidant enzyme activities. Additionally, one component derived from verectin, was also tested. In vivo, active principles exhibited significant prolongation of the life span of tumor-transplanted animals A. vera active principles exhibited significant inhibition on Ehrlich ascite carcinoma cell (EACC) number, when compared to positive control group, Moreover, in trypan blue cell viability assay, active principles showed a significant concentration-dependent cytotoxicity against acute myeloid leukemia (AML) and acute lymphocytes leukemia (ALL) cancerous cells. Furthermore, in MTT cell viability test, aloeemodin extract was found to be active against two human colon cancer cell lines. These findings are discussed in the light of the potential of Aloevera plant extracts for developing efficient, specific and non-toxic anticancer drugs that are affordable for developing countries. There are many other findings of anti-tumor effect on cancer cells.

Shiitake mushroom extract

Shiitake mushrooms have been reported [3] to have cancer-preventing properties by many researchers. One of studies was conducted by Nianbai Fang et al [3]. They observed anti proliferative effects of the shiitake mushroom extract in all cell lines using the MTT assay. Approximately 50 mg/L concentration of the fraction induced apoptosis in 50% of the population of four human tumor cell lines. Compared to malignant tumor cells, nonmalignant cells were less sensitive to the fraction for the suppression of cell growth. A 51% antiproliferative effect occurred at the highest concentration of the fraction (800 mg/L).

Agaricus blazei mushroom extract

A mushroom extract, Agaricus blazei (AB), has been reported to possess antimutagenic and antitumor effects. Ahn et al. [4] investigated the beneficial effects of (AB) consumption on immunological status and qualities of life in cancer patients undergoing chemotherapy. One hundred cervical, ovarian, and endometrial cancer patients were treated either with carboplatin plus VP16 (etoposide) or with carboplatin plus taxol every 3 weeks for at least three cycles with or without oral consumption of (AB). It was observed that natural killer cell activity was significantly higher in AB-treated group as compared with nontreated placebo group. However, chemotherapy-associated side effects such as appetite, alopecia, emotional stability, and general weakness were all improved by (AB) treatment.

Agaricus Blazei (AB) medicinal mushroom. It is used traditionally against a range of diseases, including cancer and chronic hepatitis, and has been cultivated commercially for the health food market. (AB) has recently been shown to have strong immunomodulating properties, which has led to increasing scientific interest. In a recent article Hetland et al.

[5] reviewed current knowledge as to the immunological properties of (AB), as well as clinical use in connection with infections and cancer.

Reishi mushroom extract

The dried powder of Reishi mushroom (*Ganoderma lucidum*) was popular as a cancer chemotherapy agent in ancient China. Silva D [6] recently demonstrated that Reishi mushroom inhibits constitutively active transcription factors nuclear factor kappa B (NF-. B) and AP-1, which resulted in the inhibition of expression of urokinasetype plasminogen activator (uPA) and its receptor uPAR. Reishi mushroom suppressed cell adhesion and cell migration of highly invasive breast and prostate cancer cells, suggesting its potency to reduce tumor invasiveness. Thus, *Ganoderma lucidum* clearly demonstrates anticancer activity in experiments with cancer cells and has possible therapeutic potential as a dietary supplement for an alternative therapy for breast and prostate cancer.

Among the most important traditional medicinal fungi, Reishi mushroom (Ganoderma lucidum) has been used as a therapeutic agent for the treatment of numerous diseases, including cancer, in Oriental countries. Barbieri A et al. [7] performed a study is to investigate the anti-inflammatory, anticancer and anti-metastatic activities of Ganoderma lucidum extracts in melanoma and triple-negative breast cancer cells. Their study demonstrated, for the first time, how Ganoderma lucidum extracts can significantly inhibit the release of IL-8, IL-6, MMP-2 and MMP-9 in cancer cells under pro-inflammatory condition. Interestingly, Ganoderma lucidum extracts significantly also decrease the viability of both cancer cells in a time- and concentration-dependent manner, with abilities to reduce cell migration over time, which is correlated with a lower release of matrix metalloproteases. Taken together, these results indicated the possible use of Ganoderma lucidum extract for the therapeutic management of melanoma and human triple-negative breast cancer.

Vinca rosea extract

In 2017, Das S and Sharangi AB [8] presented a thorough review of many research papers about the anticancer properties of the two famous alkaloids extracts of Vinca rosea; namely Vinblastine and Vincristine which are derived from the stem and leaf of Vinca rosea. Different percentage of the methanolic crude extracts of Vinca rosea was found to show the significant anticancer activity against numerous cell types in the in vitro condition and especially greatest activity was found against the multidrug resistant tumor types. They are also used for treatment of leukemias, lymphomas and testicular cancer.

Graviola leaf extract

Graviola derived herbal compounds have a long history of clinical use, for different types of cancer. Jeno, Gnanam, Jayadeepa and Arul [9] presented a research study on Graviola, a native of rainforest of Brazil. It has a wide potent anticancerous agent coined as Acetogenins which play a key role towards many varieties of cancer, Acetogenins are potent inhibitors of NADH oxidase of the plasma membranes of cancer cells. Potent leads were taken for the study through literature survey, major types of cancer targets were identified, the natureceuticals and the cancer protein were subjected to docking analysis, further with the help of the dock score and other descriptor properties top ranked molecules were collected, commercial drug was also selected and identified as a Test compound for the study. Later, the phytochemicals were subjected to toxicity analysis. Those screened compounds were then considered for active site analysis and to find the best binding site for the study.

In the experimental analysis, Graviola leaves were collected, and the extracted components were tested against the HeLa cell line and PC3 cell line. HeLa cells treated with 75 µg of a crude leaf extract of Graviola showing 80% of cell inhibition.

Camel milk freeze-dried powder

Habib et al. [10] have evaluated the potential of camel milk lactoferrin for its ability to inhibit the proliferation of the colon cancer cell line, HCT-116, in vitro, DNA damage and its antioxidant activities for the first time. The antioxidant capacity of Lactoferrin was evaluated by different assays, including ferric-reducing/antioxidant power assay (FRAP), free radical-scavenging activity (DPPH), nitric oxide (NO) radical-scavenging assay, total antioxidant activity and DNA damage, compared with vitamin C and rutin. Camel milk lactoferrin was found to inhibit DNA damage.

Camel milk lactoferrin inhibited the growth of colon cancer cells by more than 50% at 5 mg/mL. Also, camel milk lactoferrin was found to inhibit DNA damage.

Moreover Prof. Mansour, the author of this article freeze-dried camel milk in the lab and encapsulated it in vegetable capsules and got a free sale certificate from the FDA and tried with big number of different types of cancer patients and he arrived at excellent results.

Wormwood extract

Artemisinin is a chemical compound extracted from the wormwood plant, *Artemisia annua L.* It has been shown to selectively kill cancer cells in vitro and retard the growth of implanted fibro sarcoma tumors in rats. Singh NP and Lai HC [11] investigated its mechanism of cytotoxicity to cancer cells. It was found that DHA treatment significantly decreased cell counts and increased the proportion of apoptosis in cancer cells compared to controls. Addition of holotransferrin significantly further decreased cell counts and increased apoptosis No necrotic cells were observed. They concluded

that rapid induction of apoptosis in cancer cells after treatment with DHA indicates that artemisinin and its analogs will be inexpensive and effective cancer agent.

Black seed extract

L.Ait Mbarek et al. [12] conducted a study to evaluate the in vitro and in vivo anti-cancer effect of *Nigella sativa L.* seed extracts. The essential oil extracts were more cytotoxic against the P815 cell line than the butanol extract. Similar results were obtained with the Vero cell line. Tests on the BSR cell line revealed a high cytotoxic effect of the ethyl acetate extract compared to the essential oil. These data show that the cytotoxicity of each extract depends on the tumor cell type. In vivo, using the DBA2/P815 (H2d) mouse model, results clearly showed that the injection of the essential oil into the tumor site significantly inhibited solid tumor development. Indeed, on the 30th day of treatment, the tumor volume of the control animals was 2.5 ± 0.6 cm3, whereas the tumor volumes of the essential oil-treated animals were 0.22 ± 0.1 and 0.16 ± 0.1 cm^3 when the animals were injected with 30 µL (28.5 mg)/mouse and 50 µL (47.5 mg)/mouse per 48 h (six times), respectively. Interestingly, the administration of the essential oil into the tumor site inhibited the incidence of liver metastasis development and improved mouse survival.

Examples of pre-clinical results

The following examples are selected from more thousand cases from different countries of all types of cancer who used MG20 IMMUNE THERAPY since 1995 summarized in **(Table 1)**.

Table 1. Effect of Nano MG20 immune therapy on different types of cancer.

Case	Age	Cancer Type	Treatment Time
1	60	Non-Hodgkin's Lymphoma	12 months
2	60	Renal Cell Carcinoma	12 months
3	55	Hepatocellular carcinoma (HCC)	12 months
4	14	Acute lymphocytic *leukemia* (*ALL*)	12 months
5	50	Colon Cancer	12months
6	30	Ovarian Cancer	12 months
7	19	Hodgkin's Lymphoma	12 months
8	10	Glioma Brain Cancer	18 months
9	55,53,51	Cervical & Adenocarcinoma	12 months
10	68	Prostate Cancer	6 months

Case 1

The first example Mrs. Bseiso was 60-year-old female when Hamad Hospital diagnosed her with Non-Hodgkin's Lymphoma and she was treated by chemotherapy for one year and after treatment failure her doctor gave her 3 months to die. Her family decided to use our MG20 IMMUNE THERAPY Capsules and after 6 month-course her Hb improved from 6 to 13 and platelets from 60 to 319 and she avoided spleen removal surgery with normal LDH test and general health became much better. After another 6 months she was completely cured from cancer and she continued taking MG20 on regular basis as a preventive tool for 25 years and she died at 85 years old by heart attack.

Case 2

The second case was Dr. R. Bishtawi a 60-year-old male was diagnosed at the University of Jordan Hospital with renal cell carcinoma cancer and he was treated with chemotherapy for 4 years after which his case became worse and he got metastasis in liver, lungs and brain. He decided to start our IMMUNE THERAPY MG20. After one year his case improved 80% and he was cured after another 12 months. He continued taking MG20 for 9 years on preventive basis with excellent results. He passed away 4 years ago by a sudden stroke.

Case 3

Mr. Hanash from Syria , a 55 year old male was diagnosed with Hepatocellular carcinoma (HCC) liver cancer, 10 cm tumor size was treated with non-invasive high intensity focused ultrasound(HIFU) ablation machine for 4 days at our cancer center in ESSRA HOSPITAL in Amman, Jordan, followed by MG20 IMMUNE THERAPY 12 months curative course followed by 12 month preventive course and all his follow-up scan and blood tests including Alpha Fetoprotein (AFP) for 7 years showed he was completely cured till now.

Case 4

Mr. Saleh Zebala, a 14 years old from Jedda, Saudi Arabia, was diagnosed with Acute lymphocytic leukemia (ALL) blood cancer at M.D.Anderson cancer center in Houston, Texas and was treated by chemotherapy and bone marrow transplant followed by another chemotherapy and his case became worse and his family was asked by the hospital to send him back home soon to die in 3 weeks. His family decided to try MG20 IMMUNE THERAPY for 12 months after which he was completely cured for 14 years till now.

Case 5

Mr. I. Kuwari, a Qatari 50 year old male was diagnosed with colon cancer at Hamad Hospital and was sent to the National Hospital in London, and he was treated by a number of chemotherapy courses and after failure they informed his family he is expected to die in three months after which they started MG20 IMMUNE THERAPY for 12 months and he was completely cured for 15 years till now.

Case 6

Mrs. AL-Humaidi a 30-year-old female was diagnosed with ovarian cancer at AL-AMAL Cancer Center 14 years ago; one of the ovarian was removed by surgery and she refused to take chemotherapy for the second. Instead she started MG20 IMMUNE THERAPY for 12 months after which her scan and CA125 tumor market tests improved drastically. After her surgery her period stopped and got an early menopause but she was planning to have new kids. She took Sage and Oregano tea for3 months and she restored her period. Then she took OVARITECH our herbal tea for pregnancy for 3months after which she was pregnant and delivered a male baby. After 9 years she got a new female beautiful baby. She is still on MG20 on preventative basis till now.

Case 7

Ms. Abu-Lail a 19-year-old female from Jordan was diagnosed with Hodgkin's Lymphoma 12 years ago and was treated with bone marrow transplant and chemotherapy and after failure she started MG20 IMMUNE THERAPY capsules for one year she was completely cured till this moment.

Case 8

R.Bishtawi, a 10 year old male from Nabuls, Palestine was diagnosed with Glioma brain cancer 11 years ago and his family refused any chemo or radiotherapy and started to take MG20 IMMUNE THERAPY for 18 months and he gor complete remission till now.

Case 9

A Qatari family of 4 members; first one was diagnosed with breast cancer and she was treated by a number of courses of chemotherapy for 4 years then she passed away. After a while 2 females were diagnosed with cervical cancer and one male was diagnosed in Germany with Lung Adenocarcinoma. All three brothers and sisters refused to take any chemotherapy 13 years ago and they used MG20 IMMUNE THERAPY for 12 months and all were completely cured till now.

Case 10

Dr. Awad Mansour , the author of this article, a 68 year old was diagnosed with prostate cancer 6 years ago with PSA value of 24 and he refused to take any hormone therapy and he used MG20 IMMUNE THERAPY instead and was completely cured till this moment and he is still taking MG20 on preventive basis.

SAFETY AND TOXICITY STUDY

Toxicity study performed on mice in the animal house in Jordan University of Science and Technology showed that the composition is free of adverse effects especially on liver, kidneys, lipid and other body organs.

CONCLUSION

This patent-pending botanical nano formulation is expected to help millions of cancer cases of all types worldwide. Double blind is still needed to give more reliable results.

ACKNOWLEDGMENT

None.

CONFLICT OF INTERESTS

The authors declare no conflict of interests.

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