



CELLS

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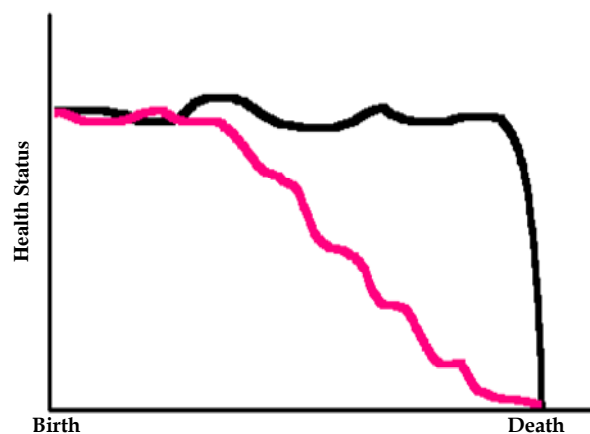
Preventive- and Anti-Aging Medicine and Tissue Repair

After completing the stem-cell based tissue repair program, some 70% of all patients with insulin-dependent, type-2 diabetes experience a significant reduction in their need for insulin, with 30% of them no longer requiring any insulin at all 60% or so of patients suffering from Parkinson's disease experience a significant relaxation in tremor and other symptoms, reporting a better quality of life and an ability to cut back or even stop taking medication after completing the program.

A response rate of no less than around 90% is achieved in patients suffering from liver cirrhosis; an impressive response rate of approximately 65% being recorded in MS patients.

CUI also treats people with stem cells for "anti-aging". One could say that by applying patients' own stem cells, the biological clock is put back by at least five to ten years.

Although aging is associated with a drop in a person's physical and mental capacity, the rate of degeneration differs. While some people in their eighties may be fit and able, others in their fifties are seen to degenerate. CUI team over the last 36 years, have developed a comprehensive program to increase the body's regenerative and self-healing capacity to slow down the aging process as illustrated by this curve.





CUI program is based on ongoing scientific findings to demonstrate that regeneration, and even neuronal regeneration, is capable of improving health by optimizing the immune system. This involves the following basic steps:

- **Hyperthermia to detoxify the body** because the body's natural response during fever is to activate the immune system, support tissue repair and increase self-healing.
- **Restore the immune system** by infusing health-promoting antioxidants, thymus peptides and vitamins that retard the metabolism's destructive oxidation and promote vitality and reduce aging.
- **Inject the patient stem cells** previously extracted from bone marrow and multiplied outside the body in a highly specialized laboratory. Once these adult stem cells have been returned to the patient, the body, primed in this way, instructs the healing process to regenerate tissue and even generate new tissue, especially in the liver, pancreas, heart muscle and nerves.

The observations made are based on peer-reviewed literature as well as ongoing scientific and clinical observations.

The description of the fundamental process through a brief historical perspective, giving consideration to biological, psychological and environmental factors, before we move on to provide a detailed overview of the efficacy and reliability of the stem cell program we use to inhibit aging and encourage regeneration.

As human beings, we have always been concerned with aging and death. No matter what the chapter in history, great minds have striven to improve the quality of life of the ill and suffering. It is only really now that we are reaping the rewards of those brave pioneers from the past.

Yet, despite all this, it is only the last century, a mere *moment* in history, that has seen the emergence of a universal truth based on insight and pragmatism, clinical trials and repetition, success and sustainable benefit.

We have now entered an age of heart, kidney, liver and lung transplants. Controversies abound about 'designer babies', genetically modified food and animals, and the almost certain imminence of human cloning. Suddenly, it seems that, once previously "locked", the inner secrets of life, growth and death, and even the mystery of human existence itself, are being opened up.



The aging process

Physiologically speaking, a new and better understanding of the aging process has emerged over the last two decades in particular. Going down the centuries, average life expectancy has increased dramatically from 25 years in ancient days to a current figure, in the industrialized world, of 79 years for men and 83.5 years for women.

Higher life expectancy is primarily attributable to cultural and medical reasons, including hygiene, diet and a greater understanding of the physiological and curative processes.

Aging is a process that involves a multitude of factors, each regulated by specific genomes for each species. Many genetic, biochemical, hormone-based, environmental and particular lifestyles have been identified as causing aging. These aspects are intimately interrelated with basic processes of life. Biological defense mechanisms have evolved which, in terms of aging, are chronically degenerative and, after reproduction, ultimately lead to death.

Key factors of human degeneration include:

- **biochemical aging** as a result of oxidation processes
- the release of **harmful free-radicals** through external influences, such as radioactivity and ultraviolet light and internal influences, including intracellular oxidation
- **hormonal aging** as hormone levels gradually decrease with age, accompanied by a loss of function and capacity in practically all organ systems
- the **immune system**, with a decline in thymus function and fall in suppressor-cell number as the individual ages
- the **environment**, with the factors well familiar from passive smoking, exposure to natural and man-made radiation, electro-smog as well as antibiotics, hormones, colorings and preservatives to name but just a few examples. Added to this, the list goes on to cover man-made malnutrition, overweight, alcohol use and drugs. Infections and 'burn-out syndrome' also take their toll.

And finally

- the **self-perception of age** in which negative age stereotypes and the perceived threat and stigmatization of old age may have a negative effect on the aging process while a positive attitude to aging may contribute to the quality and length of life.



Stem cells and their applications in medicine

Stem cells are unspecialized cells that can self-renew indefinitely and also differentiate into more mature cells with highly specialized functions. The potential of stem-cell research is enormous, offering unprecedented opportunities for developing new medical therapies to treat many diseases which, only a few years ago, were regarded as incurable. Although stem-cell research is on the cutting edge of present-day biological science, it is still in its infancy.

Given the widely differing ways in which our societies view the moral and legal status of the early embryo, the controversy over embryonic stem cells is great. Yet this controversy stops when we come to speak of using adult or autologous stem cells in medicine. CUI and their associates in various medical treatment centers, only use so-called mesenchymal adult stem cells in tissue repair.

There are important biological differences between adult and embryonic stem cells and between the adult stem cells found in different types of tissue. From the aspect of therapeutic use, the implications of these biological differences are not yet clear, and we still need to gather further data on all stem-cell types.

Typically accumulating in harmful genetic mutations, all cell lines in tissue culture change over time. We never keep stem cells alive over longer periods of time. Stem cells are multiplied over a few rounds and then applied back to the patient or deep frozen for later applications. This significantly minimizes the potential risk of stem cells mutating.

There are essentially three main sources for obtaining stem cells:

- 1) embryonic stem cells
- 2) stem cells from placenta/umbilical-cord blood
- 3) stem cells from bone marrow (adult stem cells)

Embryonic stem cells

Embryonic stem cells (ESC) are highly potent cells that can be used with little risk of rejection. They are, however, very expensive to harvest and apply. There are also many ethical problems surrounding the medical application of embryonic stem cells as they come from embryos that have been sacrificed.

Recent scientific literature reports concerns about the malignant degeneration of embryonic stem cells. In addition to the possible ethical objections, it can therefore be said that the application of embryonic stem cells is not without risk.



Stem cells from umbilical-cord blood

Stem cells from umbilical-cord blood can be harvested very easily straight after birth. Usually available in large quantities, they are best for autologous use. They are stored in a deep-frozen state at a minimum of minus 85 degrees Celsius and used at a much later stage in life. Applying stem cells from umbilical-cord blood to other human beings is more difficult as they need to be matched just like any other tissue, as for an organ transplant. This kind of stem cell is therefore best suited for autologous use.

Stem cells from (own) bone marrow

Stem cells from an individual's own bone marrow are easily obtained with little discomfort to the patient. They are adult stem cells and can be used in autologous and heterologous applications. Autologous use is completely safe and adult stem cells cannot be rejected by the immune system. For heterologous use, the cells must be matched for compatibility, as with any organ transplantation. The risk of malignant degeneration in the case of adult stem cells would appear to be extremely low, and most probably non-existent.

In quite a few centers offering treatment with adult stem cells, stem cells taken from bone marrow - the hematopoietic stem cells - are reapplied as early as 24 to 48 hours after collection. As a result, the repair capability of these stem cells is limited. Hematopoietic stem cells are used, for instance, after high-dose chemotherapy to restore the patient's bone marrow. Hematopoietic stem cells cannot differentiate into bone, pancreatic, liver or brain and nerve cells.

In contrast to hematopoietic stem cells, mesenchymal stem cells, or MSC for short, can practically turn into any other cell and thus, if applied includes hyperthermia and immune restoration, initiate tissue repair in neurological illnesses like Parkinson, multiple sclerosis, diabetes mellitus Type II, myocardial infarction, spinal cord lesions, skin ulcers and liver cirrhosis. Severe lung disease, like emphysema and renal damage, seems to respond less well to MSC application, and we are working hard on understanding why this is so and on improving our strategies to improve efficacy.

Mesenchymal stem cells form only a very small percentage of the total amount of stem cells in the bone marrow. Therefore, to have a great impact in tissue repair after isolating them, we multiply them several times so that by the end of a six to eight week period, 4 to 12 million very vital mesenchymal stem cells are usually available for application to the patient.

At CUI, we **only** use mesenchymal adult stem cells in regenerative medicine (tissue repair) and anti-aging therapy.



Production of adult stem cells in the laboratory

The hi-tech laboratories producing mesenchymal adult stem cells meet the strictest requirements of national governments and international authorities, such as the FDA (USA) and Brussels (EU). The certified laboratories operate in accordance with the highest standards of GMP (Good Manufacturing Practices) for the manufacture of medical products. CUI and its team of collaborators monitor all activities of the cell biologists and technicians working in the laboratories on a daily basis.

It is here that the mesenchymal adult stem cells are identified and isolated in a standardized and very well established procedure. After isolation, these cells, and only these cells, are multiplied while any other cell, including any possible malignant cell in the bone marrow sample, is left behind. Theoretically, if a cancer cell were to slip through the maze and become part of the MSC culture, it would be unable to multiply because the cancer cell needs a very different environment and medium. This means that the method of isolating and multiplying MSC under my supervision is extremely safe and well accepted by German and international medical authorities alike.

Fever-range, total-body hyperthermia

In recent years, a better understanding of the effects of fever has led to a renewed interest in the immunological effects in acute and chronic illness. Various organs need a specific temperature to function optimally. Depending on their metabolism and blood perfusion, each organ, with the exception of the brain stem, has a different and changing core temperature of its own (kidneys, liver, testicles, lungs, etc.).

Of all regulatory systems, the regulation of warmth is one of the most delicate and most developed. Transpiration is the body's cooling process in which perspired water evaporates; the mechanism is more effective in conjunction with airflow. In the case of fever-range, total-body hyperthermia, airflow is carefully prevented and sweating is increased. This puts the loss of warmth on hold, raising body temperature and producing fever.

There are several methods to increase core body temperature. The most common method used in fever-range, total body hyperthermia is short-wave infrared radiation because it is safe and natural, penetrating through the skin and reaching the blood flow in and under the skin; the local blood temperature is increased, spreading the warmth throughout the body and causing the core temperature to rise.

Fever has many positive effects.



- It has been discovered that when the core body temperature increases to 38.5° Celsius, the immune system more or less doubles its activity, stepping up the positive activity of immune competent cells.
- Induced fever initiates and supports tissue repair. As a result of increased blood flow and intracellular production of various cytokines, tissue repair is significantly increased.
- B-Cells are activated, which brings about an increased production of immunoglobulin.
- Phagocytosis increases: this is a more primitive but no less effective defense mechanism against foreign material, dead (cancer) cells, parasites, bacteria and viruses through incorporation and then intracellular digestion of the material.
- Fever improves the immune system's Th1/Th2 switch and activates the Th1 response. **Th1 response** reflects the ability of the immune system to trigger and strengthen its **cellular immune** activity, distinguishing between "good" and "bad" cells. **Th2** response reflects the ability to trigger and strengthen the **humoral immune** activity and usually, therefore, life-long immunity against certain infections.

This being so, we advise our patients to undergo a few sessions of “fever-range, total-body hyperthermia” to improve the way in which the body is prepared for supporting the tissue repair mechanisms triggered by mesenchymal stem cells.

Immune restoration

The immune function can be significantly improved by various immune modulators, such as Thymus peptides, antioxidants, vitamins and trace elements. Multivitamins and trace elements may be taken daily as dietary supplements. Nevertheless, some vitamins, such as Vitamin B12, are absorbed less well in older people. Therefore, applying quite a number of vitamins, antioxidants and trace elements intravenously significantly boosts the levels of these substances and contributes to optimizing the way in which the immune system works and repair mechanisms function.

While undergoing anti-aging and tissue repair treatment at the CUI, patients receive daily infusions with several of these vitamins, thymus peptides, antioxidants and trace elements from natural sources designed to suit their individual requirements. Within only a matter of days, patients normally feel the beneficial effect of these infusions and leave the clinic after a week, refreshed and energized.



Summarizing, therefore, it can be said that health, vitality, endurance, productivity and joy of life are given facts until mid-life at around the age of 40. Then, the physical symptoms of wear and tear begin to appear as a result of burnout, lack of exercise, smoking and drinking, insomnia and an unhealthy diet.

A healthy lifestyle is one important form of protection from burnout and early aging.

Lifestyle changes and the administration of certain identified vitamins, trace elements, and hormones can significantly retard aging of the physical body.

Patients undergoing the treatment have their biological age compared to their calendar age. Where applicable, anti-aging therapy is then recommended if there is any well-documented deficiency of vitamins and trace elements, or if there is a significant imbalance or decline in hormone production.

The therapeutic concept is rational, realistic and extremely safe, placing emphasis on the following key aspects:

- Simplicity and transparency in the design and optimization of a new lifestyle that focuses on self-responsibility
- Prevention of health risks
- Development of specific dietary guidelines accompanied by physical and mental exercise
- Application of “fever-range, total-body hyperthermia” to improve the efficacy of MSC with regard to anti-aging and tissue repair in the case of significant organ damage
- Prescription of dietary supplements with trace elements, vitamins and antioxidants
- Triggering of natural hormone production, or balanced hormone substitution using phytohormones true to the adage of ‘as little as possible and as much as necessary’
- Application of adult mesenchymal stem cells (MSC), and
- Mental coaching and evaluation of self-perceived age and function.

To end with a quote from Leonardo da Vinci who held that a “Life well spent is long”. There is much scientific evidence and observational experience from the Medical Center Cologne to suggest that our therapeutic concept, which essentially incorporates the elements of induced hyperthermia, immune restoration and the application of adult mesenchymal stem cells multiplied using nationally and internationally certified processes in ultrasterile, state-of-the-art laboratories, contributes not only to a long life but also to a healthy one.

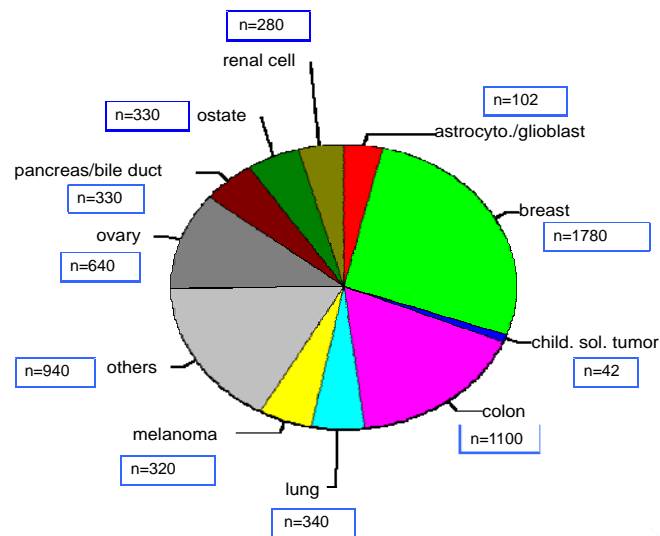


Thank you for your attention.

Application of Dendritic Cells and Adult Mesenchymal Stem Cells

CUI medical team and scientists, have extensive research and clinical experience with the manufacturing and application of dendritic cells in the oncologic patient and adult mesenchymal stem cells in degenerative diseases and anti-aging (regenerative medicine). **Dendritic cells** are the most potent cells of the immune system to discover cancerous cells and initiate the killing of these cells by the immune system. Dendritic cells are derived from patient's own monocytes which are plenty in the peripheral blood stream and therefore, easily harvested by a simple blood draw.

Over the last years, CUI and their associates have treated more than 6.000 oncologic patients of which more than 90% were end-stage patients with practically all types of cancer.



Pooled total number of treated patients with DC (n=6204) September 2007

All patients were treated with at least 4 vaccinations with their own dendritic cells (DC) and only some Grade I side effects (flue-like symptoms) were documented. Therefore, vaccinations with dendritic cells were extremely well tolerated and safe.

If combined with some form of hyperthermia, the overall response rate in this patient population with more than 90% end-stage cancer patients was 60% - 65% with about a 3% complete remission in malignant melanoma, 8% in end-stage pancreatic carcinomas to 14% complete remission in cases with stage IV glioblastoma multiforme and astrocytomas.



In 2007, several patients who were treated by us and who are in complete remission for years and years now, were on national Germany television (ARD) to tell their story.

Also, CUI has successfully applied dendritic cells in the treatments of end-stage HCV-associated liver cirrhosis. So far, all patients improved significantly when they had received vaccinations with dendritic cells to control spread of HCV infection and adult mesenchymal stem cells for liver repair.

In the peer-reviewed medical literature, hundreds of articles have been published on the safety and efficacy of dendritic cell vaccinations in cancer patients. Also here, vaccinations with dendritic cells are being portrayed as safe and very promising. The consensus among leading oncologists in the USA and EU is that in 5 years, treatments with dendritic cells will be not only standard care but also one of the most applied new therapies in oncology. **Conclusion:** Dendritic cells have been applied in the clinical setting for over eight years now, are safe, have no side effects, and are the most promising latest development in oncology and very likely, in the management of HCV infection. Attached is an overview of recent peer-reviewed articles by researchers of major research centers in the world of clinical applications of dendritic cells.

Adult mesenchymal stem cells are very potent cells which have the potential to turn into almost any tissue, thus repairing damaged organs and tissues.

Over the last three years, CUI and their medical associates have treated more than 350 patients with patients' own adult mesenchymal stem cells. Most patients were suffering from Parkinson, MS, or severe HCV-associated liver cirrhosis and infertility. The overall response rate is between 60% and 70% in usually far-advanced patients.

In addition, persons who were treated with their own adult stem cells in combination with some form of hyperthermia for wear and tear (anti-aging) could document remarkable improvements of mental and physical activities, increased sexual function (even at high age) and muscle strength, improvement of overweight and degenerative joint disease, to mention a few.

Attached is an overview of recent peer-reviewed publications on adult stem cells in the clinical use in selected patients with neurologic illnesses, cancer, and diabetes mellitus type II. All authors agree that adult stem cells are safe and have a very promising future in the treatment of patients with degenerative illnesses.

Conclusion: Adult stem cells are safe and very well tolerated when applied in a clinical setting. Not only CUI can document safety of adult stem cells but also large research centers in the USA and EU come to the same conclusion. Adult mesenchymal stem cells initiate tissue repair in many diseases but can also be successfully applied for anti-aging (regenerative medicine).



Treatment Information

1. Stem Cells and their Medical Applications

Stem cells are unspecialized cells that can self-renew indefinitely and also differentiate into more mature cells with highly specialized functions. Stem cell research has the potential to affect the lives of practically everybody around the world. This research and its clinical application is now part of any research center in the Developed World and has become regularly front-page news. Realizing the promise of stem cells for yielding new medical therapies will require us to grapple with more than just scientific uncertainties. The stem cell debate has led scientists and non-scientists alike to contemplate profound issues, such as who we are and what makes us human beings.

The application of stem cells offers unprecedented opportunities for developing new medical therapies of many diseases, which were considered as “incurable” still a few years ago. The controversy about embryonic stem cells, however, is controversial, given the diverse views held in our societies about moral and legal status of the early embryo.

Stem cell research is on the cutting edge of biological science today.

Over time, all cell lines in tissue culture change, typically accumulating in harmful genetic mutations. Cells Unlimited International never keeps stem cells alive over longer periods of time. Stem cells are multiplied a few rounds and then applied back to the patient or deep frozen for later or subsequent applications. In this way, the potential risk of stem cells mutating, is significantly minimized.

There are essentially three sources for stem cells:

- 1) embryonic stem cells
- 2) stem cells from placenta/umbilical cord blood
- 3) stem cells from bone marrow (adult stem cells)

1.1. Embryonic stem cells

Embryonic stem cells (ESC) are very potent cells and can be applied with little risk of rejection. But it is very expensive to harvest and apply ESC. In addition, there are all kinds of ethical problems around the medical use of embryonic stem cells, as they come from embryos which have been sacrificed for that reason.

Recent scientific literature reports significant concerns about malignant degeneration of embryonic stem cells. *Therefore, besides possible ethical objections, application of embryonic stem cells is not without risk.*



1.2. Stem cells from umbilical cord blood

Stem cells from umbilical cord blood can be harvested very easily right after birth. They are usually available in large quantities. But they are best for autologous use. Thus, they are stored in a deep frozen state at about -80 degrees C. and eventually used for the newborn at a much later stage in life. It is more difficult to apply stem cells from umbilical cord blood to other human beings, as usually, they must be matched like any other tissue, like in organ transplantation. It is costly and best for autologous use.

1.3. Stem cells from bone marrow

Stem cells from bone marrow are easily obtained with little discomfort to the patient. They are adult stem cells and can be applied for autologous and heterologous use. The autologous use is completely safe and cannot be rejected by the immune system. For heterologous use, the cells must be matched for compatibility, like in case of any organ transplantation. The risk of malignant degeneration in case of adult stem cells seems to be extremely low, and likely, non-existing.

Cells Unlimited uses **only** adult stem cells for autologous use for regenerative medicine (tissue repair) and “anti- aging.”

1.4. Clinical Applications of Adult Stem Cells

“if I have seen further, it is by standing on the shoulders of giants”
Sir Isaac Newton (1642-1727)

Adult stem cells can be applied in several ways: intravenously, intra-theal, locally, and through intra-arterial application.

Over the last three years, Cells Unlimited International, patients with various chronic degenerative diseases are being treated with adult stem cells, including diabetes mellitus type II, Parkinson, Multiple Sclerosis (MS), brain damage (CVA, trauma), spinal cord lesions, myocardial infarction, liver cirrhosis due to Hepatitis C infection, erectile dysfunctions, and infertility in both men and women.

Also, the after effects of radiotherapy in the oncologic patient (skin burns) and chemotherapy (prolonged bone marrow depression and Ana plastic anemia's), can be adequately addressed with stem cells.

Most patients receive a treatment with ‘fever-range, total-body’ hyperthermia just before the application of their stem cells or a loco-regional hyperthermia, depending on various factors. If appropriate, stem cells are then introduced through intra-arterial application. In this way, by combining the synergistic effects of fever and stem cells, tissue repair in the above mentioned illnesses seem to be more successful than reported by most research centers



Where stem cells are applied. As an example, usually, in most study centers, good partial Responses in diabetes mellitus have been reported. About 60% respond well ('partial responders'), with about 20-25% of these with complete response (cure). The better overall better responses are attributed to the synergistic effects when adult stem cells are being applied in combination with fever-range, total-body hyperthermia (fever therapy), local hyperthermia and infusions for immune restoration.

2. Monocytes-Derived Dendritic Cell Vaccinations in the Oncologic Patient.

Dendritic cells are the "police men" of the immune system and search constantly through all inner organs for abnormal (cancer) cells. Once they have found a cancer cell, they initiate a very powerful immune defense reaction against this cancer cell. When a dendritic cell is no longer able to recognize or initiate the killing of a cancer cell, cancer cells, which occur constantly in one's organism, can grow and spread through the body. Thus, one can say that a lack of dendritic cells or malfunctioning dendritic cells can allow cancer cells to grow and form a life-threatening illness. To make a completely new generation of vital dendritic cells is a rational way to improve the anti-cancer defense mechanisms of the immune system.

2.1 CUI Successful Approach to Cancer

Since 2001, there has been success in treating (end-stage) cancer patients with autologous, Monocytes-derived dendritic cell vaccinations. About 3.000 patients from all over the world have been treated so far with mainly solid tumors, including breast cancer, pancreatic cancer, lung cancer (both small cell and non-small cell), prostate cancer, ovarian cancer, glioblastoma multiform, HCV-associated hepatocellular carcinoma, etc. Partial response rate seems to be about 60% to 65% in stage IV (end stage) cancer patients and 3% in malignant melanoma to 12% in glioblastoma multiform.

From a simple peripheral blood draw, Monocytes are isolated and, in our laboratory, turned into millions of very vital, well-functioning dendritic cells. Vaccinations with autologous, Monocytes-derived dendritic cells are very safe and very easy to apply through a simple injection.

Quite a few patients were told they were dying and nothing could be done for them. But when they arrived at our clinic (on occasion with an ambulance air plane) they experienced a turn-around, and lived much longer and in a good quality of life (partial responders), or experienced complete response and cure in many cases. Last year, several patients were interviewed on national German television (ARD) and testified how they were told by doctors at well-known cancer centers in the USA or the EU to die and how they responded with complete resolution of their cancer and, after years of being cancer free, seem to be cured.



2.2 As a Concept for an Effective and Safe Integral Treatment of the Oncologic Patient.

Oncologic patients are usually treated with dendritic cell vaccinations in combination with fever-range, total-body hyperthermia, loco-regional hyperthermia, infusions for immune restoration, oncogenic viruses like Newcastle Disease Virus, orthomolecular medicine and life-style changes.

Over the last 8 years, significant side effects have not been observed. The only usual effect after a vaccination is flu-like symptoms which last a few hours. Flu-like symptoms are a sign that the dendritic cells have a significant impact on the immune system and usually those patients who respond with flu-like symptoms do best.

3. Summary

As practiced in Europe, the Middle East and Northern Africa, one's biological age is compared to one's actual calendar age. Health, vitality, endurance, productivity and joy for life are given facts until one reaches mid-life (around age 40). Then, usually, the first physical symptoms of wear and tear appear. Effects of burn-out, lack of exercise, insomnia and malnutrition become more evident and one cannot ignore them that easily any longer as at a much younger age.

A healthy life style is an additional protection against burnout and early aging.

As part of CUI, anti-aging therapy with adult (autologous) stem cells is then recommended.

After thorough consultation with the patient, and when a well-documented deficiency of vitamins and trace elements has been documented, or when there is a significant imbalance or decline in the hormone production, supplementation of lacking trace elements, vitamins, antioxidants and phytohormones are given which results in significant improvement of physical and mental productivity, and thus of quality of life.

In case of the oncologic patient, vaccination with dendritic cells, in combination with various forms of hyperthermia and immune restoration, have been shown to be a very safe, non-toxic and effective treatment in the battle against in practically all forms of cancer.

The therapy concept of CUI is rational and realistic and proven to be effective where other (more standard) therapies have failed or do not work at all.