8 December 2005

Description:

Use of biochemical substances for a composition for the prevention and treatment of health conditions caused by constriction of smooth muscle cells in organs of the human body

Technical field:

The present invention relates generally to the prevention and treatment of health conditions caused by constriction of smooth muscle cells in organs of the human body.

Background of the invention:

The cause of many diseases remains unknown. Among these diseases with unknown origin are most common diseases including high blood pressure, asthma, glaucoma and tinnitus. In case of high blood pressure, one of the most renowned textbooks in medicine, Harrison's Principles of Internal Medicine, states that the cause of the disease is unknown in about 90% of the patients. Worldwide several hundred million people suffer from these health conditions and the economic damage to society from not being able to treat these health conditions effectively is immeasurable.

Worldwide several million people suffer from asthma bronchiale (asthma). In its late stages asthma is a debilitating disease leading to the inability to work and to social isolation. The cause of this disease remains unknown, even though allergens, genetic disposition and psychological factors have been implicated. The common pathomechanism of this disease is an obstruction of the ventilation channels in the lung (bronchioles) and of the passages to the alveoli where the oxygenation takes place. However, the cellular mechanisms that trigger this obstruction, thereby causing asthma, is not yet understood.

Tinnitus is a form of hearing impairment that in most cases occurs suddenly and without any warning signs. It is estimated that worldwide more than one million patients suffer from tinnitus and related hearing impairment. The origin and the pathogenesis of this disease are unknown and currently there exists no effective therapy to improve the hearing capacity of tinnitus patients. Consequently, many of these patients suffer for years and decades from impaired hearing often with detrimental consequences for the ability to work and their social life.

It is assumed that a variety of apparently different health conditions occurring in different organs is caused by biochemical dysfunction of the same type of cells, called smooth muscle cells. This type of muscle cell is not susceptible to conscious control as opposed for example to the muscles of the arms or legs. Proper metabolic function of smooth muscle cells would, therefore, be a key to avoiding health problems in all those organs where smooth muscle cells play a critical functional role.

In case of asthma it is assumed that the common cellular mechanism could be found. The walls of bronchioles and alveoli channels contain a layer of smooth muscle cells. If these cells would constrict – irrespective of the trigger – the diameter of these lung ducts would decrease, leading to a decrease in ventilation and oxygenation. Thus, the typical symptoms of a patient with asthma and/or obstructive lung disease would occur.

In case of tinnitus and hearing impairment it is conceivable that the hearing impairment is caused by spasm of smooth muscle cells which form the lining of blood vessels responsible for blood supply to the inner ear and to the nerve cells mediating acoustic signals. It was further assumed that the spasm of these smooth muscle cells in the ear capillaries is caused by a lack of co-enzymes and other bioenergy molecules essential for optimum metabolic function of these cells.

There was not found any earlier description of this concept in the scientific literature.

Recent progress has been made in understanding the metabolism of cells and the role of certain biochemical compounds in maintaining their proper function. Consequently, correcting the dysfunction of smooth muscle cell metabolism would be a key to preventing and treating a variety of health conditions in different organs.

It was further found that the cellular dysfunction could be caused by a deficiency of certain biochemical compounds needed as co-enzymes in the tricarbon acid-cycle, the so-called Krebs-cycle, the respiration chain and for other metabolic functions in smooth muscle cells. The health conditions that can potentially be prevented and treated include, but are not limited thereto, the following organs and diseases:

Lungs, eye, uro-genital tract, gastro-intestinal tract, impotence, asthma and other forms of obstructive lung diseases, glaucoma and other forms of increased eye pressure, pre-menstrual syndrome, infertility, spasms of the ureter, urethra, singultus, stomach cramps, spasms of the gall duct.

Summary of the invention:

It is therefore an object of this invention to administer a composition of biochemical substances to a patient suffering from health conditions as mentioned above which consist of compounds of various vitamins, various amino acids and various trace elements.

It is a further object of this invention to administer to a patient compositions of biochemical substances consisting of at least one ascorbate compound selected from the group consisting of ascorbic acid, pharmaceutically acceptable ascorbate salts and/or mixtures thereof.

It is another object of this invention to administer a composition of biochemical substances to a patient consisting of one ascorbate compound with at least one arginine compound selected from the group of arginine hydrochlorides, pharmaceutically acceptable arginine salts and/or mixtures thereof.

It is a further object of this invention to administer to a patient a composition of biochemical substances consisting of ascorbate compounds, arginine compounds and at least one magnesium compound selected from magnesium or pharmaceutically acceptable magnesium salts and/or mixtures thereof.

It is a further object of this invention to administer to a patient the therapeutical composition of biochemical substances like Ascorbic Acid, Ascorbyl Palmitate, Beta-, Gamma-, Delta-Tocopherol-Mix, Beta-Carotene, Biotin, Calcium Ascorbate, Calcium Citrate, Calcium Glycinate, Carotinoid-Mix: (Alpha-Carot., Lutein, Zea-, Kryptoxanthin), Cholecalciferol, Chromium Glycinate, Citrus Bioflavonoids, Coenzyme Q10, Copper Glycinate, Cyanocobalamin, d-Alpha-Tocopherol, d-Calcium Pantothenate, Dicalcium Phosphate, Folic Acid, Inositol, L-Arginine, L-Carnitine, L-Cysteine, L-Lysine, L-Proline, L-Selenomethionine, Magnesium Ascorbate, Magnesium Citrate, Magnesim Glycinate, Manganese Chelate, Molybdenum Glycinate, Niacin, Niacinamid, Potassium Chelate, Pycnogenol, Pyrodoxine, Riboflavin, Thiamine, Zinc Glycinate, irrespective of dosage of these added components.

It is therefore an object of this invention to use biochemical substances for a composition for the prevention and treatment of biochemical dysfunctions of smooth muscle cells in the human body as mentioned above comprising at least one ascorbate compound, at least one

arginine compound and at least one magnesium compound in amounts effective to repair such dysfunctions.

It is a further object of this invention to use biochemical substance for a composition which comprises trace elements in conjunction with vitamins and amino acids.

It is a further object of this invention to select ascorbate compounds from the group consisting of ascorbic acid pharmaceutically acceptable ascorbate salts and/or mixtures thereof.

It is a further a further object of this invention to select the arginine compounds from the group of arginine hydrochlorides, pharmaceutically acceptable arginine salts and/or mixtures thereof.

It is a further object of this invention to select magnesium compounds from magnesium or pharmaceutically acceptable salts and/or mixtures thereof.

It is a further object of this invention to use for such a composition biochemical substances such as

Ascorbic Acid, Ascorbyl Palmitate, Beta-, Gamma-, Delta-Tocopherol-Mix, Beta-Carotene, Biotin, Calcium Ascorbate, Calcium Citrate, Calcium Glycinate, Carotinoid-Mix: (Alpha-Carot., Lutein, Zea-, Kryptoxanthin), Cholecalciferol, Chromium Glycinate, Citrus Bioflavonoids, Coenzyme Q10, Copper Glycinate, Cyanocobalamin, d-Alpha-Tocopherol, d-Calcium Pantothenate, Dicalcium Phosphate, Folic Acid, Inositol, L-Arginine, L-Carnitine, L-Cysteine, L-Lysine, L-Proline, L-Selenomethionine, Magnesium Ascorbate, Magnesium Citrate, Magnesim Glycinate, Manganese Chelate, Molybdenum Glycinate, Niacin, Niacinamid, Potassium Chelate, Pycnogenol, Pyrodoxine, Riboflavin, Thiamine, Zinc Glycinate, irrespective of dosage of these added components.

It is a further object of this invention that such composition is provided in the form of tablets, pills, injections, infusions, inhalations, suppositories or other pharmaceutically acceptable carriers and/or means of delivery.

It is a further object of this invention to administer to a patient a composition of biochemical substances whereas these formulas are provided to a patient in form of tablets,

pills, injections, infusions, inhalations, suppositories or other pharmaceutically acceptable carriers and/or means of delivery.

This concept was clinically tested for several of the above-mentioned health conditions, i.e. high blood pressure, asthma and tinnitus.

The treatment with such compositions of biochemical substances leads to at least partly considerable relaxations of smooth muscle cells resulting in the increase of artery diameter of large arteries (e.g. aorta) lowering elevated blood pressure, increasing artery diameter of midsize arteries (e.g. coronary arteries) resulting in a decrease of angina pectoris, resulting in the increase of diameter of arterioles and capillaries (e.g. arteries of the ear) leading to improved hearing, relaxation of smooth muscle cells in lung bronchioles and alveoli leading to an increase of airway diameter following a decrease of asthma symptoms, the relaxation of canal systems of the eye resulting in an increase of diameter e.g. of tear ducts decreasing eye pressure leading to a decreased risk of glaucoma and blindness, the relaxation of smooth muscle cells in ovarian tubes and uterus resulting in relaxation of muscle tissue improving fertility and decreasing PMS symptoms, relaxation of smooth muscle cells in gall ducts, ureter and urethra increasing the diameter of ducts resulting in a decreased risk of cramps caused by gall stones or kidney stones.

Having disclosed a preferred embodiment of the present invention, the following examples are provided by way of illustration only and are not attended to limit the invention in any way.

Examples:

Compositions of biochemical substances as listed below have been administered patients in the daily amounts of units of the substances shown in this example

Biochemical Substances	Units	Amount
Ascorbic Acid	mg	680
Ascorbyl Palmitate	mg	620
Beta-, Gamma-, Delta-Tocopherol-Mix	mg	22
Beta-Carotene	I.U.	1665
Biotin	mcg	65
Calcium Ascorbate	mg	1050

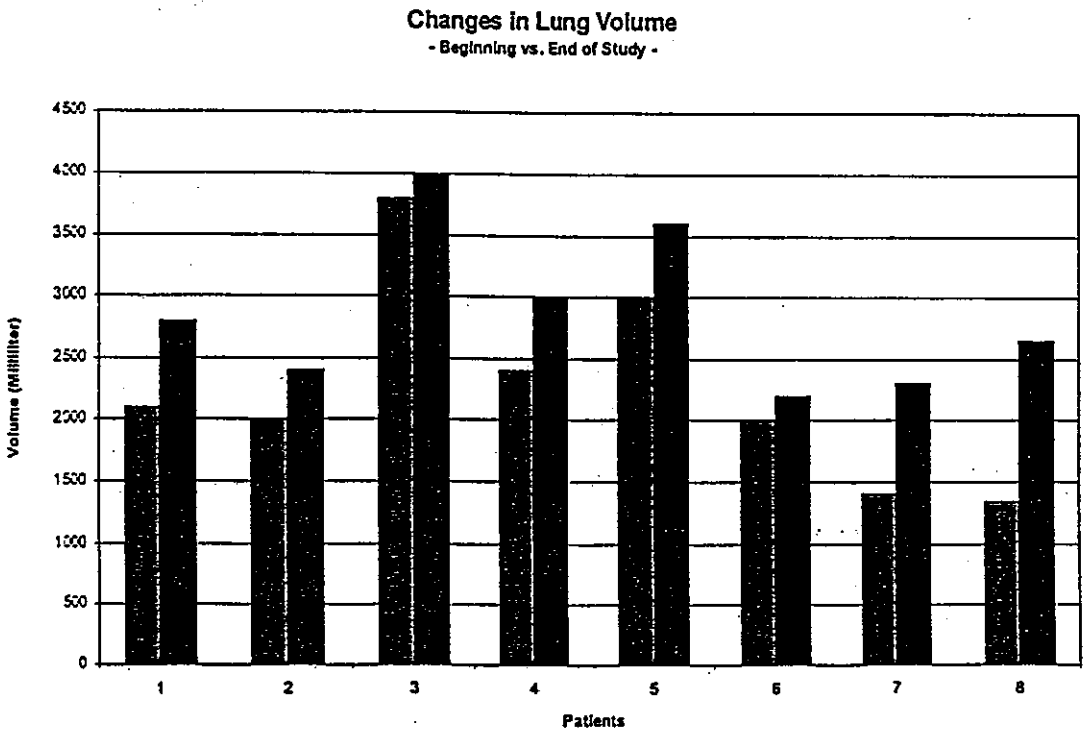
Calcium Citrate	mg	200
Calcium Glycinate	mg	35
Carotinoid-Mix: (Alpha-Carot., Lutein, Zea-, Kryptoxanthin)	mcg	50
Cholecalciferol	I.U.	130
Chromium Glycinate	mcg	10
Citrus Bioflavonoids	mg	650
Coenzyme Q10	mg	7
Copper Glycinate	mcg	330
Cyanocobalamin	mcg	20
d-Alpha-Tocopherol	I.U.	230
d-Calcium Pantothenate	mg	40
Dicalcium Phosphate	mg	15
Folic Acid	mcg	90
Inositol	mg	35
L-Arginine	mg	790
L-Carnitine	mg	35
L-Cysteine	mg	35
L-Lysine	mg	110
L-Proline	mg	110
L-Selenomethionine	mcg	20
Magnesium Ascorbate	mg	1050
Magnesium Citrate	mg	400
Magnesim Glycinate	mg	40
Manganese Chelate	mcg	1300
Molybdenum Glycinate	mcg	4
Niacin	mg	10
Niacinamid	mg	35
Potassium Chelate	mg	20
Pycnogenol	mg	7
Pyrodoxine	mg	10
Riboflavin	mg	7
Thiamine	mg	7
Zinc Glycinate	mg	7

mg = milligrams,
mcg = Micrograms,
I.U. = International Units

However, a composition of biochemical substances according to this example may be varied with individual components, others than of the formula used and irrespective of their amounts which are more than 80% identical with such substances. Further the amounts of individual ingredients provided per day may be not less than 10% and not more than 1000% of the amounts as shown in the example.

The concept of this invention was tested in a prospective clinical study with eight asthma patients. These patients received the biochemical compounds listed above as a daily dosage for a period of four months. At the beginning and at the end of the study the lung volume was measured in each patient. During the study the asthma patients increased their lung volume in average by more than 20%. The most significant result of this study was the fact that the percentage of lung volume increase was much higher for those patients with the lowest base line values which indicates that this therapy is particularly valuable with patients with severe asthma and a severe breathing impairment as shown in table 1 hereof:

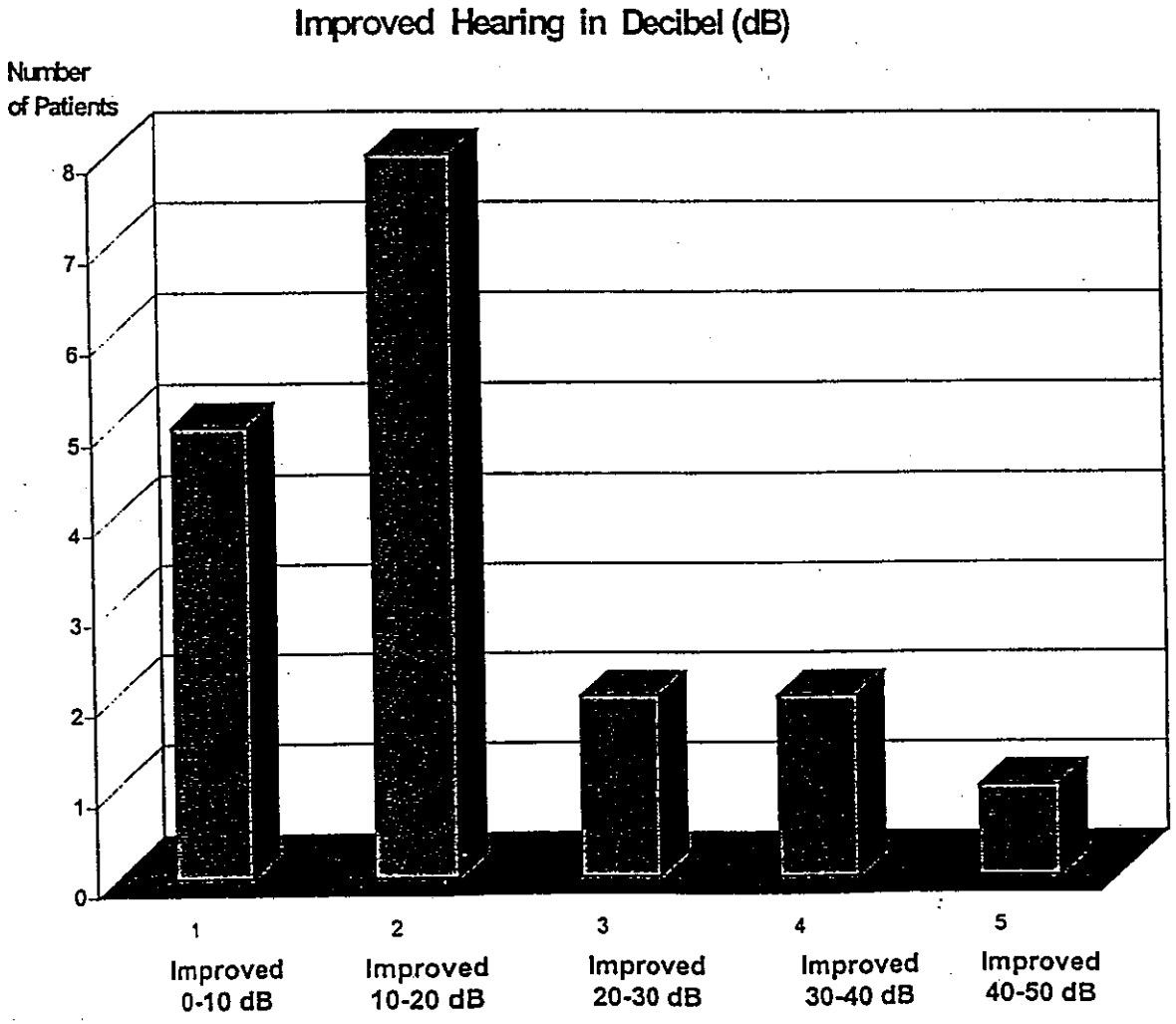
Table 1



The concept of this invention was tested in a prospective clinical study with 18 tinnitus patients for a period of four months. The hearing capacity was objectively documented by audiometry. The before/after results of the audiometry measurements are shown in table 2 hereafter:

Five patients had little or now improvement of their hearing capacity (0 - 10 decibel [dB]), eight patients had improvements between 10 and 20 dB, two patients between 20 and 30 dB, two patients between 30 and 40 dB and for one patient an improvement of hearing capacity between 40 and 50 dB was documented.

Table 2



By now it is apparent that the administering of the compositions to patients being endangered of suffering or suffering from health conditions caused at least in part by constriction of smooth muscle cells in organs of their body. Although preferred embodiments and examples have been disclosed it is understood that the invention is in no way limited thereby but rather is defined by the claims that follow and the equivalents thereof.

CLAIMS

1. Use of biochemical substances comprising at least one ascorbate compound, at least one arginine compound and at least one magnesium compound for the preparation of a pharmaceutical composition for preventing or treating impotence, asthma and other forms of obstructive lung diseases, glaucoma, pre-menstrual syndrome, infertility, spasms of the ureter, urethra, singuluts, stomach cramps, or spasms of the gall duct.

2. The use of claim 1, wherein said biochemical compounds further comprise trace elements.

3. The use of claim 1 or 2, wherein the ascorbate compounds are selected from the group consisting of ascorbic acid, pharmaceutically acceptable ascorbate salts and mixtures thereof.

4. The use of any one of claims 1 to 3, wherein the arginine compounds are selected from the group of arginine hydrochlorides, pharmaceutically acceptable arginine salts and mixtures thereof.

5. The use of any one of claims 1 to 4, wherein the magnesium compounds are selected from magnesium or pharmaceutically acceptable salts and mixtures thereof.

6. The use of any one of claims 1 to 5, wherein said biochemical substances further comprise Ascorbic Acid, AcidAscorbyl Palpitate, Beta-, Gamma-, Delta-Tocopherol-Mix, Beta-Carotene, Biotin, Calcium Ascorbate, Calcium Citrate, Calcium Glycinate, Carotinoid-Mix: (Alpha-Carot., Lutein, Zea-, Kryptoxanthin), Cholecalciferol, Chromium Glycinate, Citrus Bioflavonoids, Coenzyme Q10, Copper Glycinate, Cyanocobalamin, d-Alpha-Tocopherol, d-Calcium Pantothenate, Dicalcium Phosphate, Folic Acid, Inositol, L-Arginine, L-Carnitine, L-Cysteine, L-Lysine, L-Proline, L-Selenomethionine, Magnesium Ascorbate, Magnesium Citrate, Magnesim Glycinate, Manganese Chelate, Molybdenum Glycinate, Niacin, Niacinamid, Potassium Chelate, Pycnogenol, Pyrodoxine, Riboflavin, Thiamine or Zinc Glycinate

7. The use any one of claims 1 to 6, wherein the pharmaceutical composition is to be administered to a patient in form of tablets, pills, injections, infusions, inhalations, or suppositories.