Metal-containing topical dressings

The invention relates to the preparation of spasmolytic products to be fixed on the skin, in particular for the spasm of the muscles, based on metals.

The use of metals (rather than metal compounds, e.g. salts) is well known in antibacterial and antifungal applications. Thus, for example, GB 1,581,586 discloses metallised socks having an antifungal and antimicrobial effect. Many such applications have involved the use of colloidal suspensions of noble metals (e.g. GB 422 948 and 1 270 410) or of colloidal noble metals in combination with metal oxides (e.g. GB 474,614 and 476,376). However, no use is known for metals in applications having a pharmacological effect (i.e an effect on the body itself) rather than a chemotherapeutic effect (i.e. an effect on the invading organism).

It is well known fact that the functioning of living creatures, including humans, is controlled by various electrical, electrochemical and chemical processes; for example the currents of cerebral and nerve-activities, electrolytic and osmotic currents, diffusion and other, up-to-now not completely and essentially understood

biological processes taking place at cellular level. It is known that several diseases are caused by the absence of chemical elements or trace elements. In medicine such lacking elements are administered to the human body using different methods. In the majority of said methods the patient is confined to bed or is subjected to other longlasting therapeutical treatments, all requiring the presence and supervision of the physican.

The invention relates to a simple device suitable for a treatment which can be performed by the patient himself.

Accordingly, the invention is directed to the use of a metal or metal alloy in the preparation of a pharmaceutical dressing having spasmolytic activity in smooth or striated muscles; the use of a metal or metal alloy in the preparation of a pharmaceutical dressing for the topical administration of a trace element or other biologically essential mineral or a medicament. The invention also provides a topical pharmaceutical skin dressing comprising a metal or metal alloy in the form of powder, filings, wires, fibres, fabric, strips, and/or platelets; a carrier; and adhesive means for attaching the carrier to the skin of the human body for providing close contact between the metal or metal alloy and the skin.

It is believed that the metals used according to the invention, when put on the surface of the skin, with the aid of the sweat formed under the dressing - as with an electrolyte - orginate very weak current, which penetrates in course of the application into a certain depth of the human organism through the surface of the skin - through the pores thereof - so as to stop the muscle spasm in a short time.

Trace elements and other biologically essential elements, and other medicaments also incorporated in the dressing are aided by the current to penetrate the skin. The substance to be applied on the carrier with the metal may be a solid matter, a liquid or a gas; in the case where a liquid or gaseous matter is contained, it is to be arranged in a recipient with a permable wall, e.g. in a bag. In the case, where one or more metallic substances only are used, the spasolytic effect will be achieved out by the micro-currents obtained by the metallic elements used.

In accordance with the invention the product may be produced in a continuous form, e.g. in form of a band which can be cut in pieces to the size required, or it can be prepared in any configuration, as individual pieces.

From the point of view of the invention, all

elements and mixtures and alloys thereof are considered as metallic substances, which are able to react electrolytically with the sweat formed on the skin surface and, which are not toxic for the human organism at the levels used. The elements having a higher electrolytic potential, are the most advantageous ones, e.g. metals, expediently noble metals, copper, tin and alloys; other useful elements include zinc, manganese, cobalt, iron, arsenic, bismuth, radium selenium etc. naturally, in a quantity being tolerable for the human organism.

The metals can be powdered; the size of the particles does not influence the process, the only requirement lies in that the particles should not injure the skin surface. The metal should be present in an ordinary solid form. The invention does not envisage the use of colloidal suspensions or other microscopic forms. Plates, wires arranged in any optional geometric configuration, metal fibres, metal cloth and foils can be equally used. In particular, with noble metals it seems to be advantageous not to use a powder, since in such a manner the metal can be reclaimed and repeatedly used. As biologically essential mineral preferably sulphor or a substance yielding sulphur ions, or iodine are used. As a gas e.g. carbon mono- or dioxide, sulphur dioxide, or the mixture thereof can be used.

In a preferred embodiment the substances are applied onto the carrier in such a manner that freely adherent marginal strips are left, thereafter the part of the carrier carrying the metallic substance and optional co-ingredients is covered with a thin protective layer (e.g. a thin grease-proof paper) to be removed by means of the adhesive marginal strips in course of use.

From the technical literature dealing with electrical work safety it is well known that under the influence of the alternating current the muscles of the human body become spasmatic on the places having been subjected to the influence of the current and the person who suffered the accident - in dependence of his individual sensitivity and external circumstances - is unable to control consciously his motions above a current intensity of 5 mA. In technical literature several relating data and descriptions of experiments are to be found.

From the technical literature dealing with the prevention of accidents, it becomes obvious that in course of accidents having been suffered with direct current, the muscles of the person to whom the accident happened become fully relaxed. When applying the product having been produced by means of the process according to the invention, this latter effect has been

utilized.

In course of the experiments it can be demonstrated that even the weakest currents having been generated on the skin surface by means of the metallic substances are able to relax the spasm of the muscles and to introduce the co-ingredients.

Accordingly, the invention is based on the recognition, insofar as the case of muscle spasm, that when a metallic substance is applied onto the skin surface, on the contact surface between the metallic substance and the skin, under the influence of the continuously forming sweat, a rather weak electrolytical direct current will be induced around the grains of the metallic substance, which penetrates under the skin and so into the muscles. This effect can be increased by using a weak base or acid.

The sweat on the skin surface - functioning as an electrolyte between the grains of said metallic substance - generates an electrolytic current which intrudes under the skin surface or into the muscles lying underneath and affects the nerve-paths and hence causes the relaxation of the muscles under the dressing.

Preferably an adhesive plaster is to be used as a

carrier, since the sweat does not easily evaporate from the covered skin surface, as a consequence, efficiency can be increased. When required, electrolysis can be increased by means of a weak base or acid applied onto the carrier prior to the application of the metallic substance onto the surface of the skin. It goes without saying that only weak bases and acids not irritating or damaging the skin can be used for this purpose. It has been provied on several occasions that a muscle spasm relaxed directly the dressing was applied and within some minutes it could be essentially stopped.

It may be supposed that the effect is similar to that of acupuncture, in that when metals are placed on the places known from the acupuncture, onto the centres of higher potentials on the skin surface, or the place of the pain, and preferably an adhesive plaster is used, an effect similar to that of the acupuncture can be expected. However, in this case the treatment is free from pain and neither the skin surface nor the deeper lying layers are injured.

In case of acupuncture, the metal needles planted into the skin also generate an electrolytic potential with the fluids of the cells, the blood and other fluids, and the current is led onto the nerve-paths (probably, current generation in this case is more

efficient, as there is more electrolyte present). However, treatment can take place only in presence of the physician, while when using the product according to the invention - although the extent of the electrolytic current is less, than with acupuncture - the product can be kept on the skin for a longer period, even for weeks, without injuring the skin. In such a manner the effect can be increased to the multiple of the effect having been reached with acupuncture.

Several metallic substances differing from each other and biologically essential minerals can be applied in accordance with the invention, in the different points of the body simultaneously. As a consequence, different effects may be obtained. It can be assumed, that - similarly to the process taking place with acupuncture - as a consequence of the electrolytic process, some ions of the metallic substance or the minerals having been applied to the skin surface penetrate into certain "aimed" sites in the body due to the micro-currents and the potentials, and there change the bio-currents, and trace elements or the ions thereof can arrive at required sites. In such a manner healing can be attributed in both cases to the introduction of these elements. By means of the device having been produced in accordance with the invention, essentially

three effects can be achieved:

a) The materials having been applied onto the skin surface are able to penetrate into the cells, by diffusion, through the skin surface, i.e. through the pores thereof, by means of the adhesive plaster.

b) On the plastered surface, the skin is not exposed to the air, as a consequence sweat is formed which - together with the substance applied and the cell fluids - induces the osmotic pressure.

c) It is quite obvious that even in course of the osmosis between the membrane (the cell wall) and the two different fluids (the sweat, the substances thereon and the cell fluids) a small potential difference will arise, enhancing the ion exchange between the two liquids through the cell wall.

Probably these currents also influence to a certain extent the currents affecting the nerve-paths and promote the delivery of the material into the deeper tissues. In case of minerals and trace elements (or active ingredients of known medicaments) the effect thereof can be increased, when the powder, liquid or gas or medicament to be introduced under the skin surface and applied onto the carrier are used together with

metal particles which are able to produce a higher differential potential together with the sweat, and to accelerate in such a manner the introduction of the substance under the skin. Simultaneously, under the influence of the arising electrolytic current the previously mentioned muscle spasm relaxing effect also occurs, as a consequence, in addition to the introduction of the elements and minerals etc it becomes possible to relieve the pains.

Naturally only such substances may be applied which are compatible with the substances or medicament to be introduced and do not form toxic compounds therewith. It goes without saying that efficiency of the treatment by using the product having been produced with the process according to the invention will be influenced by the magnitude of the contacting surfaces, the pressure of contact, the duration of contact, the temperature, the properties and quantity of the materials applied and the quantity of the sweat formed.

The product can be applied in cases, in which the disease is caused by the absence of some chemical element(s), e.g. trace element(s), as well as in cases, in which spasms of the muscles occur (e.g. rheumatism, tendovaginitis, locomotor disorders, muscle spasms resulting from sport phlebitis, dyscopathia,

spondylosis, lumbago, humeroscapular periathritis, contusio, ischialgia, pains connected with scoliosis, arthrosis generalis, cochsarthrosis, myalgia, Bechterew's disease, gout, torticollis, decreasing the mucous bursa after tendovaginitis, trigeminal neuralgia, etc.). Thus, by the proper use of the product, acupuncture (Johannes Bischko, "Einfuhrung in die Akupunktur", Haug Verlag, 4th Edition, Heidelberg 1970) can be also replaced.

The products of the invention may also be applied in headache, migraine, diseases of the throat, nose and ear, rhinitis, tinnitus, geniculate neuralgia, vertigo, eye therapy, psychic diseases, sexual disturbances, pyschic instability, insomnia, spastic diseases, metabolic disturbances, allergic diseases, toothache, intercostal neuralgia, etc. (see pages 51 to 75 of the above literature).

In many cases the effectiveness of the product of the invention could be proved to a greater or lesser degree when the plaster was fixed on the places indicated in acupuncture. As examples, the following effects were observed:

- When the plaster is placed in the inner hollow under the ankle, after ca. 20 minutes a restful sleep

may be ensured. At the same time - within 10 minutes - the pulse rate will be decreased by 4 to 6. This effect may be used e.g. for alleviating rapid or anomalous heart action.

- In the case of biliary colic the literature mentioned above gives many places. During the experiments it has been stated that for achieving the effect the plaster should be fixed under the right second rib (only a few cm^2 of the plaster is enough). In this case after maximum 24 hours the bile will be discharged and the normal function thereof occurs.

- Also many places are indicated against rhinitis or for palliation thereof. From among these places the bridging of the joints of the hands on the thumb or side of the plam and the above part of the hand proved to be effective (a few cm^2). During the autumn epidemic of rhinitis the course of the disease subsided and the last yellow discharge, unpleasant phase could be eliminated by the use of the product of the invention.

- When the plaster was fixed on the inside blood vessel of the joint, the blood pressure was increased by 10 to 30 Hgmm.

The effects indicated in the literature occurred

using the 358 acupuncture point less or more intensively.

For the spasm of the muscles the result to be expected was proved, i.e. the product of the invention is effective not only on the striated skeletal muscles but also stops the spasms of the smooth muscles, e.g. the biliary colic mentioned in acupuncture, as well as the spasms of the stomach, or intestine, menstrual spasms and probably will be effective in case of myocardial and asthmatic spasms.

The product of the invention delays childbirth spasms when this is necessary e.g. owing to transportation or other reasons. After removing the plaster the spasms occur again.

In the case of operated veins the pain - on the place of the pain and swelling - may be stopped and the swelling may be decreased within 3 or 4 hours after fixing the product of the invention.

Using the products of the invention many substances, which cannot be administered or can be administered only with difficulty via the alimentary system or in form of injections, may be administered without adverse side effects. So e.g. iron in case of anemia, selenium for the prevention of cardiac infarction as well as the five

metallic 'vitamins' an insufficiency of which leads to the onset of many diseases, may be administered. Without the metallic 'vitamins' the body does not produce its prophylactic substances since they are catalysts in obtaining them (antibodies, vitamins, hormones, etc). The use of the products of the invention makes possible the prophylaxy and recovery of many diseases by using many substances and the combination thereof.

Experiments were performed for treating rheumatism and muscle spasm.

The plasters were measured in empty state and then treated with the active substance. On the edge of the plasters, bands of 5 mm were left free, so only a band of 10 cm x 5 cm i.e. 0.5 dm^2, was sprinkled with the active substance. The active substance per dm^2 is stated in the last column.

The amount of the active ingredient is not important; it may be 0.01 to 5.0 g/dm^2, preferably 0.05 to 0.6 g/dm^2, most preferably 0.01 to 0.1 g/dm^2.

The rheumatic plaster is pressed onto the skin for ca. 30 sec after having been fixed thereon.

The results are summarized as follows:

(24)

Rheumatic plaster

Sample No.	Empty Weight	Treated Weight	Weight of the active ingredient (Cu + S) g	g/dm^2
1.	1.86	1.95	0.09	0.18
2.	1.86	1.98	0.12	0.24
3.	1.88	2.00	0.12	0.24
4.	1.89	2.02	0.13	0.26
5.	1.85	1.98	0.13	0.26
6.	1.95	2.09	0.14	0.28
7.	1.93	2.10	0.17	0.34
8.	1.91	2.11	0.20	0.40
9.	1.81	2.02	0.21	0.42
10.	1.89	2.18	0.29	0.58

Plaster for stopping the muscle spasm

Sample No.	Empty Weight	Treated Weight	Weight of the active ingredient (Cu) g	g/dm^2
1.	1.88	1.885	0.005	0.01
2.	1.90	1.91	0.01	0.02
3.	1.88	1.90	0.02	0.04
4.	1.87	1.90	0.03	0.06
5.	1.89	1.92	0.03	0.06
6.	1.85	1.88	0.03	0.06
7.	1.88	1.91	0.03	0.06
8.	1.82	1.85	0.03	0.06
9.	1.90	1.94	0.04	0.08
10.	1.81	1.82	0.07	0.14

After the above treatment, the pain may relapse. In this case a plaster of 0.5 cm x 0.5 cm or that of 1 cm^2 only should be placed onto the point of pain, and the pain will no longer occur.

The following tables show the results of the clinical examinations. Using other types of the plaster the side effects indicated do not appear.

Experiments with plasters stopping the spasm of the muscle

Diagnosis	Number of the cases	unchanged	Complaints subsided	stopped	Time of occuring the effet	Side effect
myalgia	24	3	7	14	lo min to 3 days	4 dermatitis
discopathia	4	2	1	1	from 7 days	1 dermatitis
Spondylosis cervicalis	8	2	4	2	3o min to 4 days	3 dermatitis 1 itching
Lumbago	5	-	3	2	6 to 24 hours to 9 day	-
Periarthritis humero scapularis	4	1	2	1	24 hours to 8 days	1 dermatitis
Tendovaginitis	3	-	1	2	4 hours to 6 days	1 dermatitis
Ischialgia	3	1	1	1	2 hours to 5 days	-
Contusio	3	-	2	1	3o - 6o min	-
Scoliosis	2	-	1	1	from 7 days	-
Arthotis gen.	1	-	1	-	-	-
Altogether	57	9	23	25		11
%	100	15,8	4o,3	43,9		19,3

84,2

Experiments with rheumatic plasters

Diagnosis	Number of the cases	unchanged	Complaints subsided	stopped	Time of occuring the effeb	Side effect
myalgia	10	2	2	6	24 hours -7 days	4 dermatitis
Arthrosis gen.	1	1				
Tendovaginitis	2	-	2		from 6 days	1 dermatitis
Coxarthrosis	1	-	1	-	24 hours	-
Contusio	1	-	1	-	3 days	1 dermatitis
Discopathia	2	1	1	-	24 hours	1 dermatitis
Lumbago	2	1	-	1	9 days	-
Periarthritis humeroscapularis	2	1	1	-	24 hours	1 dermatitis
Spondilosis cervicalis	3	1	1	1	from 8 days	1 dermatitis
other	2	-	2	-	3 - 5 days	1 dermatitis
Altogether	26	7	11	8		1o dermatitis
%	100	26,9	42,3	30,8		38,5

73,1

CLAIMS:

1. The use of a metal or metal alloy in the preparation of a pharmaceutical dressing having spasmolytic activity in smooth or striated muscles.

2. The use of a metal or metal alloy in conjunction with a trace element or other biologically essential mineral or a medicament, in the preparation of a pharmaceutical dressing for accelerated penetration through the skin of the trace element or other biologically essential mineral or medicament.

3. A topical pharmaceutical skin dressing comprising a metal or metal alloy in the form of powder, filings, wires, fibres, fabric, strips, and/or platelets; a carrier; and adhesive means for attaching the carrier to the skin of the human body for providing close contact between the metal or metal alloy and the skin.

4. A dressing according to claim 3 in the form of an adhesive plaster.

5. A dressing according to claim 3 or claim 4 wherein the metal ingredient is present together with a biologically essential mineral in ionic or elemental form.

* C L M S *

6. A dressing according to claim 5 containing sulphur or iodine.

7. A dressing according to any of claims 3 to 6 wherein the metal ingredient comprises a noble metal, copper, zinc, tin, manganese, cobalt, iron, arsenic, magnesium bismuth selenium or radium, or an alloy or mixture thereof.

8. A dressing according to any of claims 3 to 7 further comprising a permeable bag containing a fluid medium whereby the fluid medium can also be brought into contact with the skin.

9. A dressing according to claim 8 wherein the bag contains carbon dioxide, carbon monoxide or sulphur dioxide.

10. A dressing according to any of claims 3 to 9 wherein the means for attaching the carrier to the skin comprise adhesive marginal strips.

11. A dressing according to any of claims 3 to 10 wherein the metallic ingredient is present on the carrier in an amount of from 0.01 to 5.0g per square decimeter.

* C L M S *

12. A dressing according to any of claims 3 to 11, wherein the carrier has been treated before application to the skin with a topically acceptable acid or base.
