LABIOFAM
Grupo Empresarial

Final report

***Title*: Pure experimentation with the venom of the Rhopalurus junceus scorpion at a potency of 30 CH**

Trade name of the medicine: VIDATOX® 30 CH

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Abstract

A pathogenesis study, prospective, descriptive, double blind and placebo-controlled, has been performed, with the aim of describing the emergence of clinical symptoms among healthy individuals from the administration of VIDATOX® 30 CH. A total of 20 volunteers (13 women and 7 men) from Grupo Empresarial LABIOFAM were used; these received 5 sublingual drops every 8 hours for 4 weeks, and a placebo during the fifth week. It was subsequently demonstrated that the test substance basically acts at the soma level with tropism towards the airways (both upper and lower). It also produces symptoms in the digestive and urogenital systems, the extremities, general symptoms and pain and inflammation. Administration of the placebo produced no clinical effects.

Keywords

Pathogenesy, Rhopalurus junceus, VIDATOX® 30 CH

AIM

1. To describe the emergence of clinical symptoms associated with the administration of VIDATOX® 30 CH to healthy individuals.

THEORETICAL FRAMEWORK AND JUSTIFICATION

The venom of the *Rhopalurus junceus* scorpion, a species endemic to Cuba, has been in therapeutic use here since the early 20th century. Researchers at Grupo Empresarial LABIOFAM have demonstrated that both the venom and protein fractions identified and isolated from it are significantly toxic, in vitro, to tumour cells of epithelial origin. Studies with animal models have shown that the venom has anti-inflammatory, analgesic and anti-tumour properties. Toxicity studies have revealed a low toxic potential for the

scorpion venom.

These results and the absence of references to *Rhopalurus junceus* venom in the pharmacopoeias or descriptions of its pathogenesy in published pharmacodynamics studies have led to the development of VIDATOX® 30 CH and the consequent need for a pathogenesis study of the substance.

The test substance has been administered to cancer patients, demonstrating action not only against the basic symptoms associated with the tumour site but also analgesic and anti-inflammatory effects; it produced no side effects among these patients. It improved their quality of life, increased their survival and reduced the effects of metastatic complications.

MATERIALS & METHOD

Type of trial:
Descriptive, prospective, double blind, placebo-controlled.

Subjects:
The study was performed with 20 healthy volunteers (13 women and 7 men) with technical or professional jobs, from Grupo Empresarial LABIOFAM. Their age ranges were as follows:

- 6 between 20 and 29 years
- 7 between 30 and 39 years
- 4 between 40 and 49 years
- 3 over 50 years.

All were given detailed information on pathogenesis experimentation, and were informed of the importance of recording symptoms as accurately as possible and as soon as they appear, to avoid loss of detail.

Inclusion criteria

1. Over 18 years of age.
2. Physically and mentally healthy.
3. Not having started or being under dental or allopathic treatment.
4. Reliable in terms of their ability and willingness describe their experiences during the experiment.
5. Not in the throes of major changes in their lives (personal/working relations/situation, journeys etc.).

Exclusion criteria

1. Under 18 years of age.
2. Under allopathic or homeopathic treatment during the observation and experimentation periods.
3. Use of allopathic medicines during the preceding 4 weeks.

4. Use of oral, implanted or injected contraceptives during the preceding 3 months.
5. Surgery during the preceding 2 months.
6. Pregnancy or lactation.
7. Allergy to the substance to be tested.

Criteria for volunteer withdrawal

1. Severe adverse effects requiring treatment.
2. Treatment following accident or symptoms unrelated to the substance being trialled.
3. Proven failure to observe the required frequency of administration

Origin and preparation of the homeopathic medicine

The *junceus* species of the *Rhopalurus* genus is endemic to Cuba and is distributed throughout the island. It belongs to the family Buthidae in the order Scorpiones, within the class Arachnida of the phylum Arthropoda. The results of a biochemical analysis of its venom are summarised below:

Parameters	*Results*
Proteins	Positive
Peptides	Positive
Amino acids	Positive
Lipids	Positive
Carbohydrates	Positive
Proteases	Positive
Gelatinases	Negative
Hyaluronidases	Negative
Phospholipases	Negative
Sodium	Positive
Potassium	Positive
Magnesium	Positive
Copper	Positive
Zinc	Positive
Protein concentration	6 -20 mg/mL
Identification (HPLC*) Retention time (min.)	Peak 1: 36.755 ± 0.234 Peak 2: 35.167 ± 0.214 Peak 3: 29.898 ± 0.186 Peak 4: 16.603 ± 0.234 Peak 5: 9.357 ± 0.185

* High Performance Liquid Chromatography

Having obtained and analyzed the venom pool and checked its organoleptic, physical, chemical and microbiological properties, it was processed according to Schwabe W. [1] The finished product consisted of a 30 CH dilution (30th centesimal potency of Hahnemann) in a 33% hydroalcoholic solution.

Dosage and administration

During the first four weeks, 5 sublingual drops of the test substance were administered every 8 hours either 15 minutes before or 15 minutes after food. The same regime was adopted in the fifth week for the administration of the placebo. The test substance was delivered to each volunteer weekly; one of these bottles contained placebo, whose labelling was understood only by the pharmacist who prepared them, consistent with double blind, placebo-controlled methodology.

Data collection

Each individual recorded and described his/her experience on a daily basis during the administration period, in the experiment diary. The information generated was then collected and organized by symptom (objective and subjective), adopting a basis and order in accordance with Kent's Repertory.

Bioethical considerations

Bioethical principles were followed throughout the research, including those of independence, goodwill, absence of malice, and dignity and safety of the volunteers. The identities of the volunteers were protected, after obtaining their informed consent to the purely scientific use of the results.

RESULTS

Under the regime described, the test substance caused a disordering of vital functions among healthy subjects, characterized by a series of symptoms, as reflected in the following table:

Table 1. ***Symptoms as described by the volunteers during the pathogenesis study***

Section	Symptom	Code	Individuals affected
Mental	Anxiety with hurriedness both on walking and while working or performing household chores during the day	17, 16	2
	Euphoria and improved intellectual and working performance	10,16	2
	Fear of contracting an incurable disease, of death, of the future	17, 11	2

Head	Pain that starts after administration, increases and spreads from the forehead, affects the temples with throbbing, lasts a few minutes and clears up quickly. The cycle repeats with each administration.	13, 16, 19, 20	4
	Stabbing pain in the forehead and crown, accompanied by marked photophobia	20	1
Face, eyes, nose, mouth & ears	Acne-type eruptions	5, 20	2
	Mouth aphthas that worsen with acidic foods, cold and hot drinks, which produce pain and a burning sensation	12, 17	2
	Reddened and inflamed eyes	4, 11	2
	Non-catarrhal conjunctivitis	4	1
	Reduction in earache (initial symptom)	12	1
	Itching around the eyes	11	1
Throat	Burning sensation	5, 8 9, 20	4
	Pain aggravated by swallowing food and eased by drinking tepid water.	2, 4, 5, 20	4
Respiratory	Shortness of breath on effort; tiredness	9	1
	Cough that starts dry and becomes expectorating	9	1
	Pain at the base of both lungs, aggravated by inspiration	9,10	2
	Sensation of occupied lung	9,10	2
	Coryza	5, 8, 11, 17	4
	Rhinitis - either unilateral or bilateral	5,11	2
	Improvement in initial respiratory symptoms (breathlessness on effort)	10	1
	Emergence of prodromal symptoms of influenza	4, 5, 9, 17,19, 20	6
Breasts & chest	Swollen, inflamed breasts	2, 5	2
	Pain on palpation	2, 5	2
Digestive	Burning sensation in the stomach	8	1
	Nausea and vomiting	8	1
	Sensation of gas-filled stomach	6, 8	2
	Stomach-ache	8	1
	Constipation with ineffective efforts	6	1
	Rectal prolapse and slight bleeding	6	1
	Burning pain on attempts to defecate, aggravated by effort	6	1
Renal	Frequent urination	2, 5, 17	3
	Abundant urine on each occasion	2, 5	2
	Difficulty in urinating and small amounts at a time	17	1
Genitals	Slight discomfort in the prostate area	17	1
	Sensation of inflammation in the perineal region	17	1
	Early menstruation	2	2

Extremities	Improvement in existing pain (initial symptom) aggravated by movement of the cervical region	5, 11	2
	Improvement in existing pain (initial symptom) aggravated by movement of the shoulders	5	1
	Improvement in existing pain (initial symptom) aggravated by movement of the knee	16	1
	Improvement in existing pain (initial symptom) aggravated by movement of the legs	9	1
	Improvement in existing pain (initial symptom) aggravated by movement of the toes	11	1
	Improvement in inflammation (initial symptom) in the painful areas	5, 11	2
	Pain extending downwards from the hip to the leg, aggravated by movement	5	1
	Pain extending upwards from the ankle to the knee, aggravated by movement	20	1
Skin	Small eruptions on the back, around the breasts and buttocks	20	1
	Small eruptions with itching	11, 20	2
	Cutaneous rash	11	1
General	Restorative sleep	10, 17	2

The reactions of the volunteers compiled at the end of the pathogenesis trial were qualitatively varied. The ability of the test substance, unlike the placebo, to cause functional imbalance in the respiratory, throat and face/eyes/nose/mouth/ears and other sections was demonstrated.

Given the diversity of the volunteers' responses, it was also possible to identify other symptoms, related to the digestive and urogenital systems, extremities and of a general character with pain and inflammation. Based on the observed effects and taking account of experience gained in other pathogeneses[2, 3], it was evident that their emergence results from the energetic imposition of the medicine.[4]

CONCLUSION

VIDATOX® 30 CH acts basically at the soma level with tropism towards the upper and lower airways. It also causes digestive and urogenital imbalances and imbalances in the extremities with pain and inflammation.

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Signature sheet

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