Revista Electrónica de portales medicos.com

ISSN 1886-8924

Volumen VI. Número 8 - Primera quincena de Mayo 2011

Clinical response of acute febrile patients with the treatment of the nutritional supplement VIUSID®

Universidad de Ciencias Médicas de la Habana
Hospital - Faculty Dr. Salvador Allende

Title: Effect of the natural product VIUSID on patients admitted into hospital with acute febrile disease of diverse etiology.

Authors: Dr. Guillermo Hernández Mojena* Dr. Mayra R. Carrasco García*
Dr. C.M. José Luis Giroud Benítez** Dr. María de los Á. Gómez Alarcón***
Dr. Francisco Rosell Conde***

* Consulting Professor at ISCM-H. 2nd Degree Specialist in Geriatrics
** Doctor in Medical Science. 2nd Degree Specialist in Neurology
*** 1st Degree Specialist in Geriatrics. Master's in Sciences

Correspondence to: Professor Guillermo Hernández Mojena
Consulting Professor at ISCMH. Master's in Sciences
Email: ghmojena@infomed.sld.cu

Guillermo Hernández Mojena
Carmen 67 entre Parraga y F Poey Víbora 10 de Octubre
Telephone number: 641-2397

Mayra R. Carrasco García
Calle A, número 8023 entre Segunda y Dolores Reparto Dolores, San Miguel del Padrón, Havana, Cuba
Telephone number: 6916300. Email: mayra.carrasco@infomed.sld.cu

Jose Luis Giroud Benítez
3era · 426 entre 2 y 4 Apto 6A. Plaza
Telephone number: 8331548. Email: mendoza@infomed.sld.cu

María de los Á. Gómez Alarcón
Pasaje C Nro 11. Entre Goss y Pasaje B Víbora 10 de Octubre
Telephone number: 6416820. Email: maria.gomez@infomed.sld.cu

Francisco de Asís Rosell Conde
28 Nro. 356 apto 9 Entre 25 y 27
Telephone number: 8367328. Email: f.rosell@infomed.sld.cu

Summary

Objetive. To evaluate the effect and safety of the nutritional product VIUSID in the treatment of acute febrile desease of diverse etiology. **Method.** There were two groups randomly created to determine the effect of VIUSID. The sample size
was 200 patients, 100 in the experimental group who received conventional treatment with VIUSID and 100 in the control group receiving only conventional treatment. Both groups were evaluated in three different times (first, third, and sixth day). **Results.** It was found clinical improvement in all symptoms in less time and greater amount for the group taking VIUSID and better response of leukocytes. **Conclusions.** VIUSID as adjunctive therapy produced a faster improvement of symptoms and a decrease of leukocytes in patients in the experimental group compared with the control group.

Resumen

Objetivo. Evaluar el efecto del producto nutricional VIUSID en el tratamiento de la enfermedad febril aguda de etiología diversa. **Método.** El tamaño de la muestra fue de 200 pacientes, 100 en el grupo experimental, que recibió el tratamiento convencional más VIUSID y 100 en el grupo control que recibió sólo el tratamiento convencional. A ambos grupos se les realizó evaluaciones en tres tiempos (al inicio, al tercer y al sexto día). **Resultados.** Se comprobó mejoría clínica en todos los síntomas en mayor cuantía y menos tiempo para el grupo que tomó VIUSID y una mejor respuesta de los leucocitos. **Conclusiones.** Se produjo una mejoría más rápida de los síntomas y una disminución de los leucocitos en los pacientes del grupo experimental en comparación con el grupo control.

Introduction

In our climate and living conditions, given the Epidemiological Contingency table concerning the increase in the number of cases of acute febrile disease in the hotter and rainy seasons, which is when patients are more likely to be carriers of influenza, dengue, infection caused by H1N1 virus, flu, different respiratory complaints, among other viral etiologies, alternative natural treatments with

antioxidant properties must be assessed so as to improve the quality of life of those suffering from aforementioned disesases. (1) (2) (3)

According to published reports on the results of clinical trials carried out, glycyrrhizinic acid, which is contained in VIUSID, has proven to have a number of therapeutic properties that are especially beneficial for patients with liver diseases such as Hepatitis C, fatty liver disease, and Cirrhosis of the liver. (There are also international publications on the results of using VIUSID in various countries on patients with dengue, H1N1, and even AIDS, in which no type of intolerance or adverse reaction has been reported whilst it is being administered). That is why the working group at our centre decided to use the food supplement VIUSID in order to improve the clinical and immunological symptoms of the patients admitted into hospital with acute febrile disease of diverse etiologies. (4) (5) (6) (7)

METHOD

A randomized pilot study in two parallel groups was carried out to determine the effect of VIUSID in the treatment of febrile syndromes of diverse etiologies. The study was organized in the febrile syndrome unit at the Hospital Clínico Quirúrgico Docente Dr. Salvador Allende during the period of October 22 to December 22, 2009. The sample was made up of 200 patients; 100 in the treatment group that were given conventional treatment plus VIUSID 1 sachet containing 4 g every 8 hours and 100 in the control group that were only given the conventional treatment. Both groups had the treatment for six days, hematology tests were carried out on them, and a questionnaire was completed with their personal data (**Annex 1**) on the first, third, and sixth day of their admission.

Inclusion criteria

- Patients of both genders.
- Aged between 16 and 99 years.
- Informed consent to take part in this clinical trial, signed and attached as an annex to this paper.

Exclusion criteria

- Patients who do not agree to take part in the clinical trial.
- Patients who were being treated with another antioxidant.

Data analysis and processing methods and techniques to be used

The automated data base in the SPSS program version 16 was set up. The quantitative variables were expressed by means of the measures of central tendency and dispersion (the mean, the median, minimum and maximum values, 95% confidence intervals) and the mean values for separate samples were then compared.

The Chi-square test was used to analyse the clinical variables. A 5% significance level was provided for in all cases. The results are presented in tables and graphs.

Content of each 4 g sachet of VIUSID

Malic Acid 0.666 g, Glucosamine 0.666 g, Arginine 0.666 g, Glycine 0.333 g, Glycyrrhizinic Acid 0.033 g, Ascorbic Acid 0.020 g, Zinc Sulphate 0.005 g, Calcium Pantothenate 0.002 g, Pyridoxal 0.0006 g, Folic Acid 0.0066 mg, Cyanocobalamin 0.0003 mg, Neohesperidine 0.005 g, Lemon 0.666 g, Mint 0.033 g, Honey 0.833 g, Guar Gum 0.68 g.

Results

In **graph 1**, significant differences are observed between the groups in terms of the clinical symptoms at the beginning of the clinical trial ($p>0.05$). At the start of the clinical trial, there are significant differences in the corresponding hematology variables as shown in **table 2**: leukocytes ($p=0.002$), lymphocytes ($p=0.001$), monocytes ($p=0.001$), and platelets (0.04).

The second and third measurements from both groups were taken so that they could be compared with the initial measurements of the two groups. (That is to say, the averages of the differences or the changes were calculated).

In **graph 2**, significant differences between the groups with regard to the clinical symptoms are observed: fever ($p=0.000$), headaches ($p=0.000$), arthralgia ($p=0.000$), myalgia ($p=0.000$), and lack of energy and weakness ($p=0.01$), with prevalence in the control group.

In **Table 2**, statistically significant differences are observed in the hematological variables of the two groups, namely hemoglobin (p=0.004) and the neutrophils (p=0.04). In the treatment group, there was a drop-reduction in hemoglobin and the neutrophils, which was detected when the 2nd measurement was compared to the first one, namely 0.306 g/l for hemoglobin and -5.24% for the neutrophils.

In contrast, in the control group, there was a 0.258 g/l increase in hemoglobin, and a 17.7% increase in the neutrophils.

Graph 3 shows the significant differences between the groups in terms of the clinical symptoms: lack of energy and weakness (p=0.001) and respiratory symptoms (0.001), with prevalence in the control group.

Table 3 shows the statistically significant differences between the groups with regard to the hematological variables hemoglobin (p=0.02) and the leukocytes (p=0.01). The comparison between the third measurement and the first measurement for the treatment group shows a drop-reduction in hemoglobin and the leukocytes; 0.145 g/l for hemoglobin and -2.58 10^3/l for the leukocytes.

In contrast, there was a 0.277 g/l increase in hemoglobin and an increase of 3.2 10^3/l for the leukocytes in the control group.

Discussion on the results

Some of the symptoms that are experienced along with a fever are more obvious than others, such as chronic tension-type headaches that radiate from the neck and produce pain behind the eyes which gets worse with head or eye movements and with pressure to the paravertebral muscles of the neck area. (8) (9)

Myalgia and arthralgia are also common symptoms of a fever especially in the calf muscles and the muscles of the lumbar region that sometimes prevented the person in question from walking and standing up. These symptoms mean that more severe conditions such as leptospirosis, whose epidemic genius is more prevalent in summertime, are ruled out. (10)

The existence of respiratory symptoms was mainly due to infections in the respiratory system caused by different agents that are quite frequent at this time of the year. These include the common cold, influenza, undifferentiated upper respiratory tract disease, and

acute viral and bacterial pharyngitis, that were prevalent in a large number of cases in this last fever contingency. (11) (12)

On comparing the resulting average of both groups in the last sample taken which was compared to the first one, patients that were given VIUSID had a greater satisfactory response in terms of the improvement in the clinical symptoms, which were alleviated quicker compared to those of the control group.

This food supplement provides essential antioxidant nutrients that are needed for the immune system to work properly. (13)

The activation of the components of VIUSID, increases to a large degree the power of the biological functions of all of them, such as the antiviral and antioxidat action, without modifying or changing the molecular structure, and significantly builds up the organism's defences, which explains why the clinical improvement in the treatment group was faster.

There was a significant improvement observed in the patients who had virus-related respiratory disorders that were taking VIUSID. The antioxidant substances in this preparation eliminate the negative effect of the free radicals which appear in all infectious processes. Moreover, as it contains glycyrrhizinic acid (inhibits virus replication, both DNA and RNA viruses), it stops the virus multiplying. Thus it is an effective way of treating viral processes.

VIUSID stimulates the production of Interleukin-12 in macrophages, enhancing the production of interferons which then stimulates alveolar macrophages and consequently increases their phagocytic and antimicrobial properties. (14)

Lack of energy and weakness, no interest in learning or getting up in the morning were common symptoms that accompany these disorders and last a long time even after the infection, mainly viral, has been stopped, just as we often see in daily medical practice.

It is worthwhile mentioning that the figures from the overall leukocyte count were better in the hematological tests carried out on the treatment group compared to those from the control group, as the figures from the leukocyte count dropped quicker and went back to normal on the sixth day, which suggests that the infection was controlled better and this therefore confirms the product's modulatory effect that helps regulate the elements that make up the immune system. (15) (16)

Bibliography

1-Casasbuenas J. Sindrome febril. En: Manual de Urgencias en Medicina Interna. Asociación Colombiana de Medicina Interna. Ediciones Act Méd Col. Santafé de Bogotá, 1994.

2-Vickery DM. Fever of unknown origin. An algorithmic approach. JAMA 1977 238:2183.

3-Durack DT, Street AC. Fever of unknown origin-reexamined and redefined. En: Remington JS, Swartz MN, editors. Current clinical topics in infectious diseases. 2003.

4-Vilar Gomez E, Gra Oramas B, Soler E, Llanio Navarro R, Ruenes Domech C. interferon alpha 2b and ribavirin in patients with chronic hepatitis. Liver Int. 2007 Mar;27(2):247-59.

5-Arase Y, Ikeda K, Murashima N, et al. The long-term efficacy of glycyrrhizin in chronic hepatitis C patients. Cancer 1997; 79: 1494–500.

6-Lin JC. Mechanism of action of glycyrrhizic acid in inhibition of Epstein-Barr virus replication in vitro. Antiviral Res 2005; 59: 41–47.

7-Zell R, Bergmann S, Krumbholz A, Wutzler P, Dürrwald R. Ongoing evolution of swine influenza viruses: a novel reassortant. Arch Virol. 2008; 153(11):2085-92.

8-Gillers HM, Worrell D. Fevers. En: Tropical and Geographical Medicine. 2ed. New York, McGraw Hill, 1990.

9-Savio E, Cabrera S, Pirez MC, Piñeyro L. Consideraciones clínico terapéuticas sobre la influenza. En: valoración multidisciplinaria hacia la preparación de un plan nacional de contingencia. Montevideo: OPS; MSP, 2004; 7-14.

10-Pandemina H1N12009 update 86. http://www.who.int/csr/don/2010_02_5/en

11-Cambridge: Blackwell, Wang XQ, Li HY, Liu XY et al. The anti-respiratory syncytial virus effect of active compound of Glycyrrhiza GD4 in vitro Zhang Yao Cal 2006; 29: 692–694.

12-Baba M, De Cleroq S, Nakashima H, Yamamoto N. 1988. Mechanism of inhibitory effect of glycyrrhizin on replication of human immunodeficiency virus (HIV). Antiviral Res 1998; 10: 289–298.

13-Di Mambro VM, Fonseca MJV. Assays of physical stability and antioxidant activity of a topical formulation added with different plant extracts. J Pharm Biomed Anal. 2005; 37: 287–295.

14-Di Mascio P, Murphy M, Sies H. Antioxidant defense systems: the role of carotenoids, tocopherols and thiols. Am J Clin Nutr 1991;53:194s-200s.

15-Roche Ltd. Vitamins and Fine Chemicals Division. Business Unit Carotenoids. Basle, Feb 1992.

ANNEX 1
Questionnaire for patients with febrile syndrome

1. Patient's initials: I_I_I_I_I
2. Inclusion number: I_I_I_I
3. Date of inclusion: I_I_I / I_I_I / I_I_I (day/month/year)
4. Medical history_____
5. Meets the inclusion and exclusion criteria: Yes I_I No I_I
7. Age: I_I_I years 8. Gender: Male: I_I Female: I_I

9. Clinical symptoms

Fever of 38 degrees or more	Yes I_I No I_I	Coughing with phlegm	Yes I_I No I_I
Headache	Yes I_I No I_I	Rash	Yes I_I No I_I
Arthralgia	Yes I_I No I_I	Diarrhoea	Yes I_I No I_I
Myalgia	Yes I_I No I_I	Nausea	Yes I_I No I_I
Weakness & lack of energy	Yes I_I No I_I	Vomiting	Yes I_I No I_I
General discomfort	Yes I_I No I_I	Anaemia	Yes I_I No I_I
Anorexia	Yes I_I No I_I	Prostration	Yes I_I No I_I

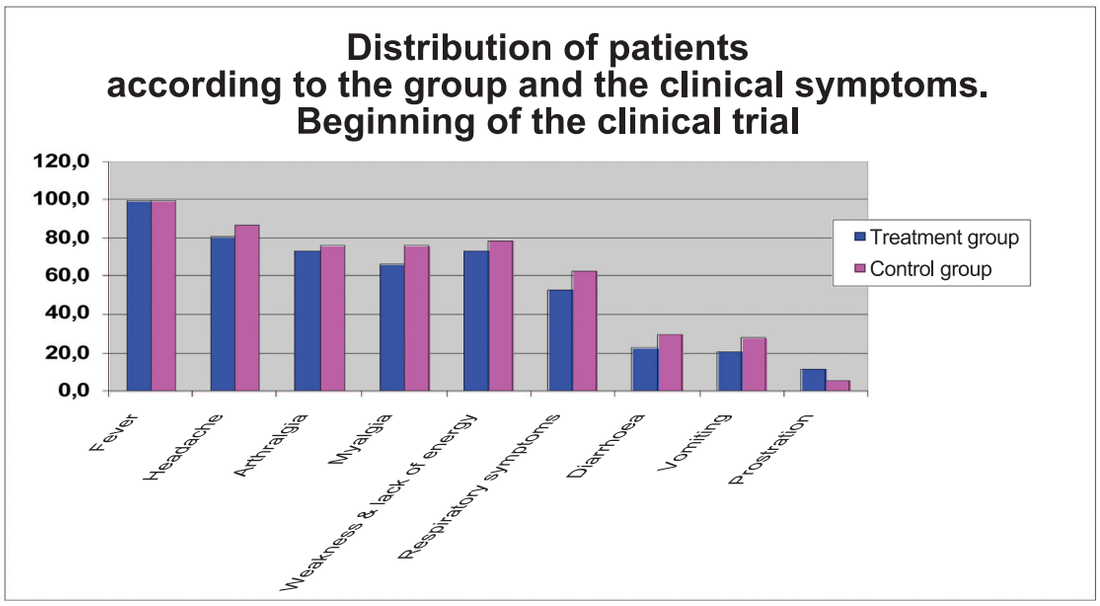
11. Hematology test: (Date I_I_I / I_I_I / I_I_I)

Completion date: I_I_I / I_I_I / I_I_I (day/month/year)

Examination	Result
Hemoglobin	I_I_I_I g/dl
Total Leukocytes	I_I_I.I_I_I x 10^9 /l
Neutrophils	I_I_I.I_I_I x 10^9 /l
Hemoglobin	I_I_I_I g/dl
Hematocrit	I_I_I_I vol %
Lymphocytes	I_I_I.I_I_I x 10^9/l
Monocytes	I_I_I.I_I_I x 10^9 /l

Graphs and Tables

Graph 1. First measurement



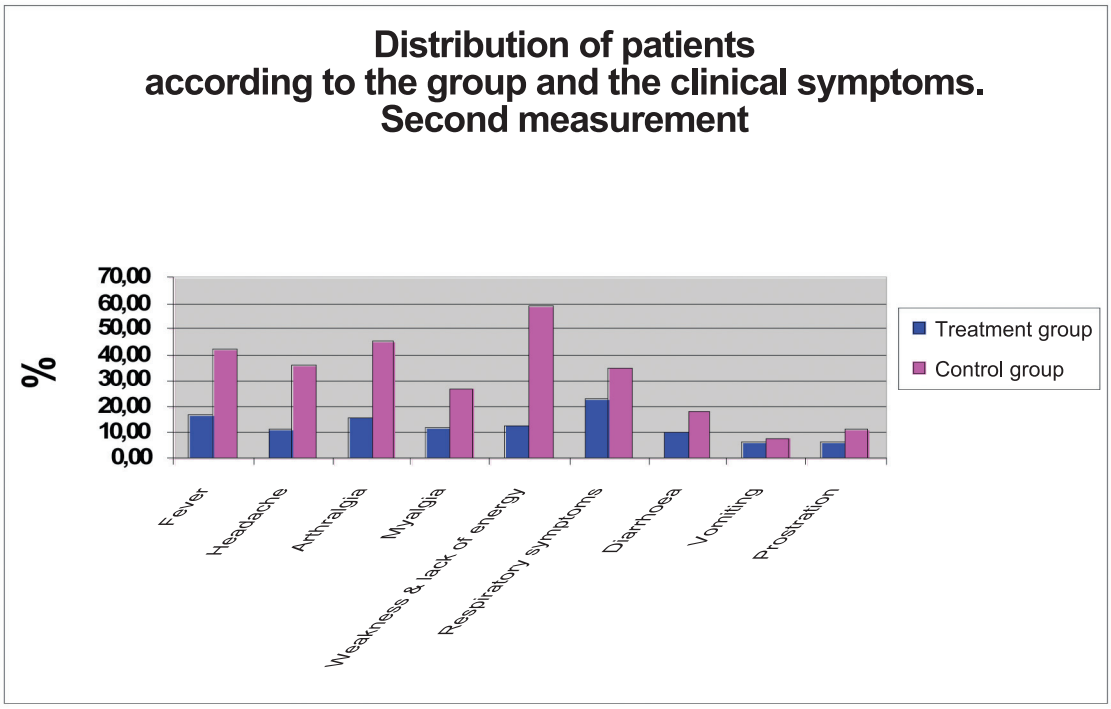
Source. Febrile Syndrome Questionnaire

Table 1. Hematology test at the beginning of the clinical trial

	mean	SD	mean	SD	
Hemoglobin; g/dl	12.6	1.4	12.9	1.4	0.210
Leukocytes; 10^9/l	9.6	7.4	7.0	3.1	0.002
Neutrophils; %	71.6	13.4	68.8	11.4	0.050
Lymphocytes; %	21.6	11.8	30.0	11.8	0.001
Monocytes; %	3.7	2.4	4.8	2.5	0.001
Hematocrit; vol./%	0.4	0.0	0.4	0.0	0.90
Platelets; 10^9/l	269.2	84.6	244.8	78.9	**0.04**

Source. Febrile Syndrome Questionnaire

Graph 2. Second Measurement



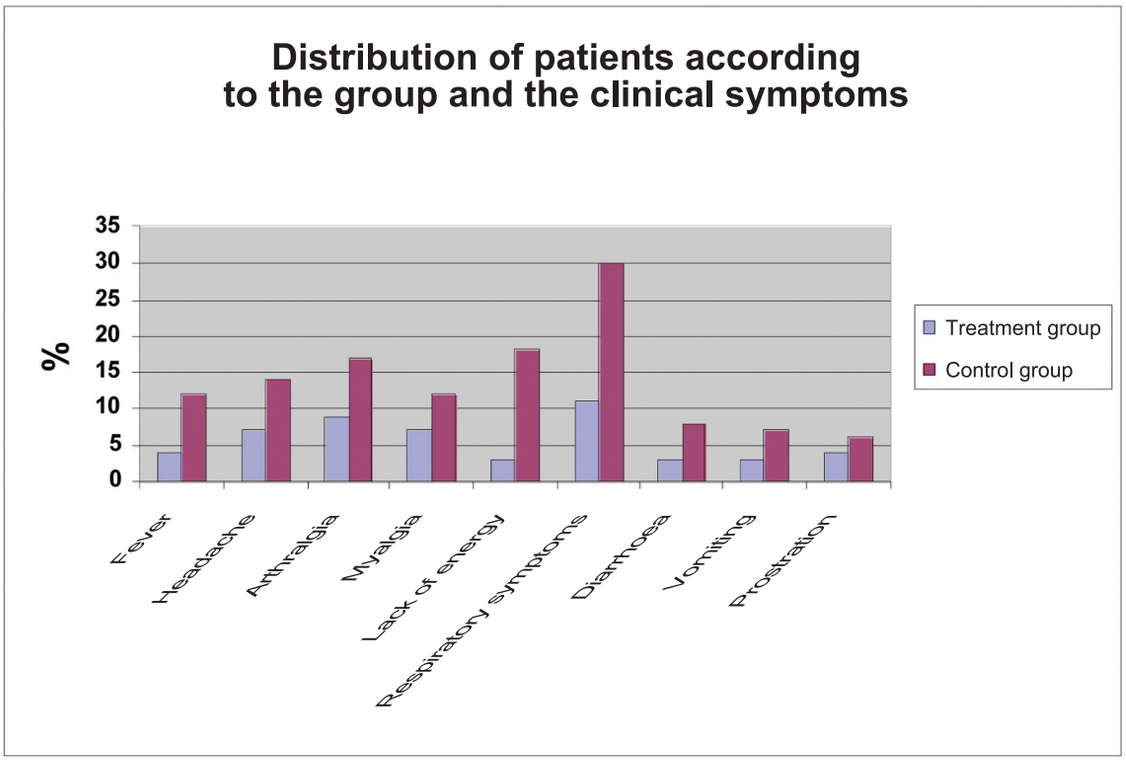
Source. Febrile Syndrome Questionnaire

Table 2. Hematology test Second measurement

	mean	SD	Mean	SD	
Hemoglobin; g/dl;	-0.3060	1.3	0.2580	1.2	0.004
Leucocytes; 10^9/l	-1.89	6.05	-0.81	2.8	0.110
Neutrophils; %	-5.24	17.6	-10.4	17.7	0.04
Lymphocytes; %	5.8	13.6	6.5	15.7	0.7
Monocytes; %	0.35	3.5	-0.24	2.7	0.180
Hematocrit; vol./%	-0.041	0.07	0.0031	0.04	0.39
Platelets; 10^9/l	-21.4	64	1.18	100	0.06

Source. Febrile Syndrome Questionnaire

Graph 3. Third measurement



Source. Febrile Syndrome Questionnaire

Table 3. Hematology test Third measurement

	mean	SD	mean	SD	
Hemoglobin; g/dl	-0.145	1.3	0.277	1.2	0.02
Leukocytes; 10^9/l	-2.58	6.9	-0.637	3.2	0.01
Neutrophils; %	-8.26	16	-11.07	16	0.223
Lymphocytes; %	8.69	13	7.85	14	0.664
Monocytes; %	-0.052	2.6	0.217	4.2	0.586
Hematocrit; vol/%	0.008	0.05	0.006	0.05	0.710
Platelets; 10^9/l	-4.88	93.6	-8.08	90.6	0.806

Source. Febrile Syndrome Questionnaire

CLOSE