US 20110224140A1

(19) **United States**

(12) **Patent Application Publication**

BELLUSCIO

(10) **Pub. No.: US 2011/0224140 A1**

(43) **Pub. Date: Sep. 15, 2011**

(54) **HUMAN CHORIONIC GONADOTROPIN (HCG) ORALLY OR FOR INJECTION FOR THE TREATMENT OF MOOD DISORDERS AND ALCOHOLISM**

(76) Inventor: **DANIEL OSCAR BELLUSCIO**, Buenos Aires (AR)

(21) Appl. No.: **13/048,737**

(22) Filed: **Mar. 15, 2011**

Related U.S. Application Data

(63) Continuation of application No. 12/007,596, filed on Jan. 14, 2008, now abandoned.

Publication Classification

(51) **Int. Cl.**

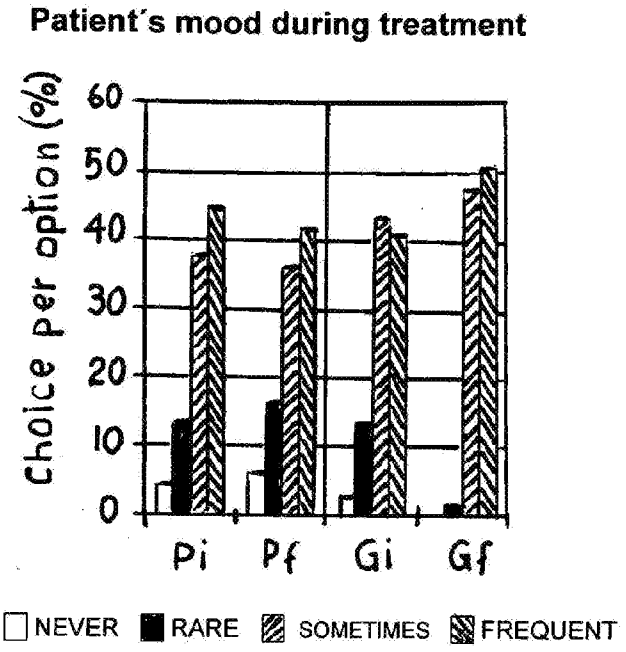
A61K 38/24	(2006.01)
A61P 25/32	(2006.01)
A61P 25/00	(2006.01)

(52) **U.S. Cl.** **514/9.7**

(57) **ABSTRACT**

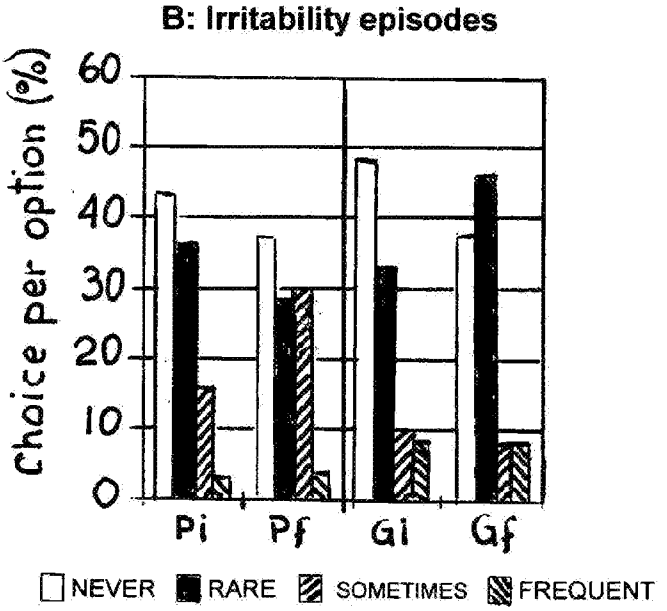
An HCG preparation for oral administration or for injection used either as a simple dilution or coupled to albumin or a cyclodextrin therapeutically effective in the treatment of mood disorders including (but not limited to) neurosis, irritability, depressive states and borderline states. HCG preparation as above described is also effective in the treatment of all types of alcoholism.

FIG. 1



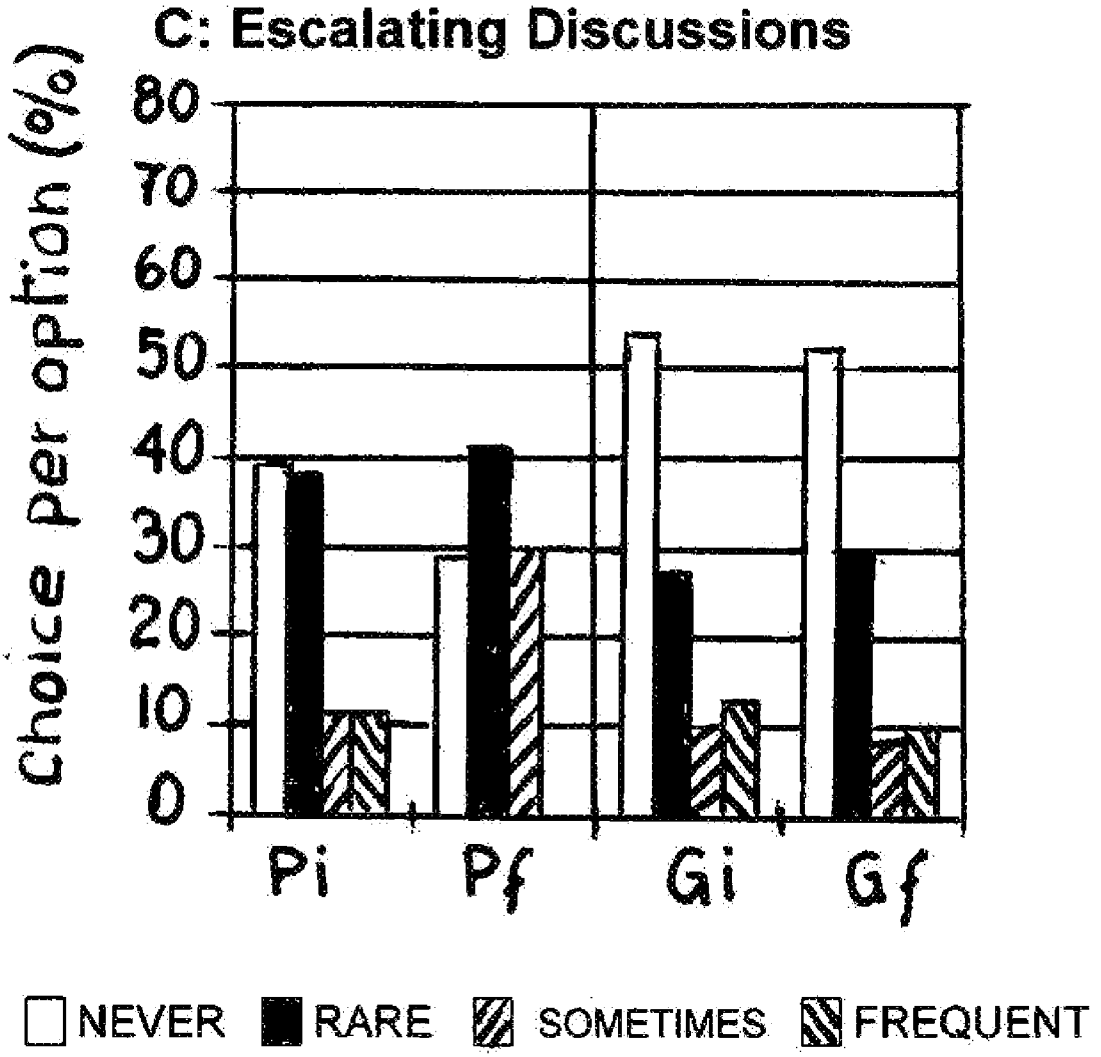
Pi: Placebo initial – Pf: Placebo final
Gi: Gonadotrophin initial – Gf: Gonadotrophin final

FIG. 2



Pi: Placebo initial – Pf: Placebo final
Gi: Gonadotrophin initial – Gf: Gonadotrophin final

FIG. 3



Pi: Placebo initial – Pf: Placebo final
Gi: Gonadotrophin initial – Gf: Gonadotrophin final

HUMAN CHORIONIC GONADOTROPIN (HCG) ORALLY OR FOR INJECTION FOR THE TREATMENT OF MOOD DISORDERS AND ALCOHOLISM

[0001] The present application is filed as a continuation application and claims priority of application Ser. No. 12/007,596.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] This invention relates to human chorionic gonadotropin (hcg) orally or for injection for the treatment of mood disorders and alcoholism, particularly HCG to be used as medical therapy for effective treatment of mood disorders as well as highly effective treatment of alcoholism.

[0004] 2. Description of Prior Art

[0005] (HCG) was found and described for the first time' in pregnant women's urine by Ascheim and Zondek, about 1927. It was later found that this substance is produced in human placenta. Since it' was discovered in 1927, it was recommended for countless uses. At present, it is mostly prescribed for fertility problems and cryptorchidism (failure of both testicles to descend in children). HCG is currently supplied as a lyophilized substance for injection. Material is drawn from pregnant women's urine. It is available from several international pharmaceutical laboratories. About 1954 an English investigator published a paper containing his own experience with this substance in the treatment of obesity. The paper was welcomed and accepted by scientists generally until 1974-75, when the method became obsolete.

[0006] The method provided by the above-mentioned investigator had several problems: it was for injection, caused immunity after treatments longer than six weeks, had some secondary effects, such as fluid retention, among others.

BRIEF SUMMARY OF THE INVENTION

[0007] An HCG preparation for oral administration or for injection used either as a simple dilution or coupled to albumin or a cyclodextrin therapeutically effective in the treatment of mood disorders including (but not limited to) neurosis, irritability, depressive states and borderline states. HCG preparation as above described is also effective in the treatment of all types of alcoholism. HCG oral preparation provides the same therapeutic effects as psychotropic substances commonly used in the treatment of the disorders as described above, but does not have the same technical and pharmacologic problems as such drugs. Moreover, it is an alternative to be considered in the cases of alcoholism since there is no effective treatment for this condition yet. The preparation can be used for long periods without secondary undesired effects.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] The figures included in the present application are charts representing the results of the test conducted to show the results of the use of HCG in the present invention.

[0009] FIG. **1** is a chart of the tests performed showing patient's mood during treatment.

[0010] FIG. **2** is a chart of the test performed showing irritability episodes

[0011] FIG. **3** is a chart of the test performed showing the arguments held during treatment.

DETAILED DESCRIPTION OF THE INVENTION

[0012] The standard lyophilized preparation supplied by pharmaceutical laboratories is used for HCG preparations. Originally, HCG is supplied as a lyophilized powder containing 2,000 to 10,000 International Units (IU) of HCG per vial. IU concept stands for an agreement whereby each IU represents the quantity that is adequate to cause maturity of an egg in experimental animals.

[0013] For the purposes of this invention, HCG is dissolved in 1% physiological saline with or without addition of human albumin or different buffers, to be administered as an injection or orally, placing it under the tongue and maintaining it there for an easier absorption by the rich sublingual venous plexus. Dilutions are prepared in such a way that each cubic centimeter of diluted HCG corresponds to a certain quantity expressed as IU.

[0014] Once Solution has been prepared in sterile conditions, it can be stored in the refrigerator for periods of 4 to 7 days. This period of time can be extended (7-10 days) if the solution is stored under cold chain conditions. Once the solution has been absorbed by the sublingual mucosa, a fraction of HCG is absorbed and carried into the circulation until it reaches the regulation centers of hypothalamic region, which contain appetite and satiation centers and fatty tissue metabolism.

[0015] Oral administration is more advantageous than injections one since it is easier to administer and equally effective. Since treatment is innocuous, it can be used for several months without problems and with equally effective results.

EXAMPLE

[0016] The following study was conducted in order to validate 105 obtained clinical results: Seventy (70) women were Screened (double blind study was conducted at site Gynecology Section. After signing the required consent, they where divided into two groups: Group A received saline alone, whereas group B received two different concentrations of HCG. The study was designed based on double blind study methods: neither the volunteers nor the staff knew who received placebo and who belonged to the HCG-administered group. The numbers assigned to each volunteer showed the type of substance (placebo or HCG) to be administered. The envelopes containing the codes were opened at the end of the study.

Determinations

[0017] The following tests were carried out during the study:

[0018] A—Laboratory studies (Day O), and after the study.

[0019] B—Irritability test during treatment, which was evaluated through a questionnaire to be completed by patients once a week, including Hamilton test for depression and questionnaire for mood disorder evaluation. All evaluations were performed by the same observer throughout the treat-

ment period in order to avoid observation differences due to different observers performing evaluations.

Study Period

[0020] Study period was five weeks, at the end of which the envelope containing the codes for each patient was opened, and the data obtained were used for statistical studies (regression and variance's studies).

Data Analysis

[0021] The following studies were performed:

[0022] Data were entered in a database and compiled in ASCII format.

[0023] Frequency, media, standard deviation and standard error analyses were conducted. Variance, co-variance and multiple regression analyses were conducted.

Results

[0024] Volunteers completed a questionnaire concerning their mood during treatment.

[0025] The following statistical differences between both Groups were found: HCG-administered patients felt better during study period ($p<0.03$ on the third week of treatment, and $p<0.01$ by the fifth week of treatment.

[0026] They had better and deeper sleep periods ($p<0.06$ on the third week of treatment.) They showed greater acceptance of points of view that were different from their own ($p<0.01$ on the fifth week of treatment). They were less irritable ($p<0.001$ from the fourth week of treatment). They got less upset every time things were not as expected ($p<0.05$.) They were less willing to argue for trifles ($p<0.05$.) They were less inclined to argue loudly ($p<0.005$ on the fourth week of treatment.) After four weeks' treatment 65% of the treated patients reported that they were in a better mood, less irritable, had longer and better sleep periods, had a tendency to avoid arguing for trifles, and their familiar relationships were more friendly.

[0027] On the other hand, volunteers that had problems with excessive alcoholic drinking reported they did not feel the urge to drink and that they could restrain from drinking even when social pressures inciting to do so. This group also reported that they were able to refrain from alcoholic beverages drinking despite heavy social pressure

Approximately 10% of the patients completely quit alcoholic drinks spontaneously during treatment.

Conclusions

[0028] Nowadays mood disorders are a very common pathology in society, and the several or recommended treatments are not always implemented due to moderate to severe secondary effects. The use of HCG has demonstrated efficacy in the treatment of mood disorders without revealing undesirable effects, as well as the capacity to be administered for long periods. On the other hand, alcoholism is a serious social health problem for which there are no available therapeutic solutions. Since oral HCG has no secondary effects, its administration for the treatment of chronic alcoholism is an excellent and innocuous therapeutic aid.

1. A method of treating a human patient having mood disorders comprising the oral administration of an effective amount of a solution of human chorionic gonadotropin (hCG), to said human patient in need thereof.

2. The method of claim **1** in which a solution of hCG powder dissolved in a pharmaceutically suitable buffer is orally administered.

3. The method of claim **1** in which a solution of hCG powder dissolved in physiological saline is orally administered.

4. The method of claim **1** in which a solution of hCG powder dissolved in 1% pharmaceutically suitable buffer, is orally administered.

5. A method of treating a human patient having mood disorders comprising the parenteral administration of an effective amount of a solution of human chorionic gonadotropin (hCG), in a sterile injectable formulation to said human patient in need thereof.

6. The method of claim **5** in which a solution of hCG powder dissolved in a pharmaceutically suitable buffer is parenterally administered.

7. The method of claim **5** in which a solution of hCG powder dissolved in physiological saline is parenterally administered.

8. The method of claim **5** in which a solution of hCG powder dissolved in 1% pharmaceutically suitable buffer is parenterally administered.

9. A method of treating a human patient suffering from alcoholism comprising the oral administration of an effective amount of a solution of human chorionic gonadotropin (hCG), to said human patient in need thereof.

10. The method of claim **9** in which a solution of hCG powder dissolved in a pharmaceutically suitable buffer is orally administered.

11. The method of claim **9** in which a solution of hCG powder dissolved in physiological saline is orally administered.

12. The method of claim **9** in which a solution of hCG powder dissolved in 1% pharmaceutically suitable buffer, is orally administered.

13. A method of treating a human patient suffering from alcoholism comprising the parenteral administration of an effective amount of a solution of human chorionic gonadotropin (hCG), in a sterile injectable formulation to said human patient in need thereof.

14. The method of claim **13** in which a solution of hCG powder dissolved in a pharmaceutically suitable buffer is parenterally administered.

15. The method of claim **13** in which a solution of hCG powder dissolved in physiological saline is parenterally administered.

16. The method of claim **13** in which a solution of hCG powder dissolved in 1% pharmaceutically suitable buffer is parenterally administered.

* * * * *