

STUDY ON THE EFFECT OF CANOVA IN HEALTHY VOLUNTEERS

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With the objective to evaluate the effect of the CANOVA medicine in healthy volunteers, the following protocol was established:

Volunteers:

Ten male and 6 female volunteers were recruited, with ages ranging from 25 to 52 years old, with an average of 38, all without systemic illnesses or important pathologies that could invalidate the results of this study, all of them graduated from high school. None of them was under any kind of medical treatment. None of the women was menopausal, pregnant or breast-feeding.

Study format:

All the volunteers were informed about the scope and limitations of the study, and accepted to be included in it, and a written consent was signed. It was recommended to all the volunteers to take the medication for at least 7 days before the beginning of the study. On the first day of study (day 0), each volunteer received 5 ml of CANOVA by intravenous way, and simultaneously, 10 drops of the product by sublingual route, repeating the sublingual dose everyday for 14 days.

Every 48 hours each volunteer was submitted to the questionnaire attached, adding to a specially developed chart only those positive data. Also, weight, heart rate, blood pressure, breath rhythm and retinoscopy were recorded, adding the data to a specially developed chart.

At the beginning of the study, before receiving the first round of treatment, each volunteer was submitted to a complete blood cell count, glycemia, urea, creatinine, ALT, AST, CK, LDH, urine and ECG. These parameters were evaluated also at 7 days after the beginning of the treatment, and right after the end of it.

RESULTS

From the 16 recruited volunteers, all of them finished the study, although only 10 (6 men and 4 women) made the last lab tests indicated, and the ECG.

It is good to clarify that, from the 6 recruited women; only 4 got their menstruation during the extension of the study. However, yet out of protocol, it was advised that the 6 female volunteers should register their menstruation rhythm during 3 consecutive cycles.

The results of the questionnaire showed the following:

GENERAL STATE: no changes.
 CARDIOVASCULAR SYSTEM: no changes.
 RESPIRATORY SYSTEM: no changes.
 URINARY SYSTEM: no changes.
 SKELETAL SYSTEM: no changes.
 ORGANS OF THE SENSES: no changes.
 SKIN AND SOFT TISSUES: no changes.
 DIGESTIVE SYSTEM: 9 out of 10 men and 5 out of 6 women related an increase in the appetite, that was more evident after 48 hours from the beginning of the treatment, but only 6 out of 10 men, and 2 out of 6 women related an increase in the amount of food they ingested. To the question about presenting a preference for some kind of food in particular, half men and half women answered that between the 4th and 6th days they had a strong desire to eat beef.
 PHYSICAL OUTPUT: 6 men and 2 women related that, alter the 5th day, they felt more active physically, performing physical movements better than before. INTELLECTUAL OUTPUT: some volunteers (4 men and 2 women) related that, from the 4th day on, they presented better focus at work, coinciding that the same volunteers affirmed that, also, they retained more easily data and numbers.
 AFFECTIVE ASPECTS: 6 men and 2 women related to be in a better disposition alter 6 days of treatment. Also, 2 men and 4 women related to be more communicative by the end of the study. Four men and 3 women related to not so streded. When they were asked to be more precise in this information, they related that they were “not nervous”, “accepted things more calmly”, “did not have problems”, were in “a good mood” and were “not stressed”.
 MOTIVATIONAL ASPECTS: no changes.
 FUNCTIONAL SEXUAL ASPECTS: 2 women and 7 men related an increase in their sexual desire. From the 7 men, 3 related an improvement in their sexual performance. These activities were noticed to begin from the 4th to the 6th day after the beginning of the study. Four men related, by the end of the study, that they presented longer-lasting erections than usual, getting the erection more easily and presenting a bigger number of daily erection episodes, especially at night.
 ORGANIC SEXUAL ASPECTS: No changes. The female volunteers from this study related that, outside the evaluation system, that after 3 consecutive sexual cycles, there were no changes in their menstruation rhythm.

In brief, the volunteers who related subjective changes in their organisms and/or in their social aspects did not relate undesirable or adverse effects, instead only good, agreeable effects.

In the following table, a summary of the data related by the volunteers can be appraised:

| QUESTION | MALE | FEMALE | TIME* |
|--|------|--------|-----------------|
| Did you have appetite? | 9/10 | 5/6 | 2 ^o |
| Did you have preference for some kind of food? | 5/10 | 3/6 | 10 ^o |

| | | | |
|---|------|-----|-----|
| Was there an increase in the amount of food ingested? | 6/10 | 2/6 | 6° |
| Was there an improvement in your physical output? | 6/10 | 2/6 | 12° |
| Were you more communicative? | 2/10 | 4/6 | 12° |
| Did you have a good mood? | 6/10 | 2/6 | 6° |
| Were you more tranquil? | 4/10 | 3/6 | 10° |
| Were you more focused? | 4/10 | 2/6 | 10° |
| Could you remember easily information and numbers? | 2/10 | 2/6 | 8° |
| Did you have more sexual desire? | 7/10 | 2/6 | 6° |
| Was there an improvement in your sexual performance? | 3/10 | | 6° |
| Did you have more erections? | 4/10 | | 10° |

*: time, expressed in days, when most of the volunteers related the changes.

The results of the blood parameters did not show significant changes in any of the volunteers in any time alter the beginning of the treatment, obtaining similar values to the basal blood count (the exams previous then the treatment). The same took place with the urine analysis, the glycemia, urea, creatinine, ALT, AST, CK and LDH. The results of the blood count, urine analysis and enzymes profiles showed data considered as normal.

The ECG showed that, in 6 men and 3 women, there was a decrease in the heart rate, not significant statistically, with normal records, in the exam made by the 7th day after the beginning of the treatment, compared to the basal register. From these volunteers, only 4 men and 2 women made the exam on the 14th day, maintaining the decrease in the heart rate. The other volunteers did not show any changes in the ECG performed.

In the physical evaluation of the volunteers, there were no semiotic changes. In the retinoscopies performed, there were no changes detected. In the breath rhythm there were also no changes.

However, there were some small changes in the blood pressure, heart rate and weight.

Blood pressure: in 7 men and 2 women it was detected, from the 8th day of treatment on, a small decrease both in the systolic as in the diastolic pressure of about 10 mmHg. The values on the other volunteers did not show any difference. It is good to clarify that the blood pressure records were obtained in the morning, and also that, after so many interviews, the volunteers were familiar with the person examining, what could cause a more relaxed state during the evaluation.

Heart rate: 6 men and 3 women showed a small decrease in the heart rate from the 6th day alter the beginning of the treatment that was maintained through the end of the study. This decrease was not statistically significant. **Weight:** 7 men and 2 women showed a weight gain ranging from 2 to 4 kilograms with an average of 2.5 by the end of the study. The weight gain happened gradually since the 6th day after the beginning of the treatment. It is important to clarify that other 3 female volunteers, after they

started feeling hungrier, considered that they could gain weight, so, they voluntarily restricted their food ingestion.

CONCLUSIONS.

- The administration of CANOVA on the way it was performed in this study did not lead to undesirable or adverse effects.
- During the period of the study, none of the volunteers should suspend the treatment.
- The secondary effects related by the volunteers were, in all cases, pleasant.
- The administration of CANOVA on the way it was performed in this study caused a minimum hypotensive effect, with a decrease of the heart rate of some volunteers, although these changes were not statistically significant and were always within values considered normal.
- Other effect that may be considered positive is the weight gain.
- These secondary effects had, in common, the fact that they are related to a better organic metabolic response, with immediate repercussion on their social activities.
- The effects started happening quickly after the beginning of the treatment, but how long they lasted is unknown, since this data was not compromised within the objectives of this present study.
- There were no significant changes between men and women.
- In order of importance, according to the frequency, the positive secondary effects were:
 1. Increase of the appetite.
 2. More sexual desire, especially in men.
 3. More physical output.
 4. Better mood.
 5. Better intellectual output.
- Other secondary effects with no clinical relevance were the change in the heart rate, the decrease of the blood pressure and the weight gain.