FINAL REPORT

FINAL REPORT PROSPECTIVE, SINGLE-CENTER AND CLOSED CLINICAL STUDY TO , CERRADO Y UNICÉNTRICO TO EVALUATE THE CLINICAL EFFICACY AND SAFETY OF MEDICAL DEVICE INSTALIFE BY INDUSTEX IN PATIENTS DIAGNOSED WITH BACK PAIN, SCIATICA OR SIMPLE PIRIFORMIS SYNDROME.

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CONFIDENCIAL

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CLINICAL RESEARCH ETHICS COMMITTEE

	CEIC:	CEI de los Hospitales Universitarios Virgen Macarena y Virgen del Rocío
	Code favorable opinion:	2015/269
	Date of opinion:	30 Oct 2015

SYNOPSIS OF THE STUDY

CLINICAL RESEARCH OF INSTALIFE BY INDUSTEX

Device name: INSTALIFE

Device description: Instalife is a brace that fits under the knee made of neoprene with metal anchors (sliding belt). It has a rigid plate for applying pressure on the sciatic nerve.

Objetives: The purpose of this study is to evaluate the elimination or improvement of low back pain, sciatica and piriformis syndrome that relate only to the sciatic nerve.

Population of subjects: Patients diagnosed with low back pain, sciatica or piriformis syndrome mechanical or simple related to the sciatic nerve between 25 and 65 years old.

Estructure: Prospective, closed, controlled, single-center clinical study designed in accordance with the guidelines of ICH Good Clinical Practice and FDA; ISO 14155 (2011): standard clinical research of medical devices; and national requirements (Local Health Department).

Sample size: Up to fifty volunteers are recruited for the study.

Concurrent control: In the experiment includes 50 volunteers to serve as study group. The study will be conducted for about four weeks - an initial consultation in which the patient's condition will be evaluated without undergoing the treatment, a second consultation at 2 weeks of treatment where changes are checked in pain study group (treatment Instalife), and finally a final consultation in which the changes are checked in pathology

Variable performance: Device placement is evaluated, and its ergonomics.

Assessment methods: Percussion test sciatic nerve and Lasegue test will be performed on volunteers to determine the initial state of the disease and improvement in pain after treatment with Instalife.

Safety Variables: Safety will be assessed taking into account the previous experience of the product on the market, especially the possible skin reactions caused by the use of the product.

Promoter of the Study: Industex SL

Ethical Committee of Clinical Research (CEIC): CEI University Hospitals Virgen del Rocío and Virgen Macarena

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1 .- INTRODUCTION

Low back pain is localized in the lower back. Sciatica pain is caused by compression of the sciatic nerve or its roots. Piriformis syndrome is a condition in which the piriformis muscle is a contraction or spasm, and irritates the sciatic nerve that passes under.

Considering the length of the pain, low back pain (lasting no more than six weeks and chronic when it exceeds 6 weeks) is classified into acute.

According to the characteristics of pain is classified as mechanical or simple it is one that has no warning signs, worse by movement and subsides with rest and specific mechanical or not is secondary to infectious processes, tumor, inflammatory disease, etc., usually day and night, does not yield even worse with rest and you can wake up at night.

Low back pain in Spain cause more than 2 million visits in primary care and major cause of temporary disability. The prevalence is 60-80% in a lifetime and annual incidence is 5-25% with a peak age of 25-45 years. (*Patología dolorosa de columna vertebral. Dolor lumbar y ciático. Ruta asistencial de integración AP-E. Servicio de Salud de Castilla la Mancha, 2007*)

Overall, it is estimated that 5 to 10% of patients with low back pain have sciatica, while the prevalence of low back pain throughout life is 49 to 70%. It is estimated that the annual prevalence of sciatica related to disc disease in the general population is 2.2%. There have been few personal risk factors and occupational, including age, height, mental stress, smoking, and exposure to vibration of vehicles. The evidence on the association between sciatica and sex or physical condition is conflicting. (*Autor: Dres. B W Koes, M W van Tulder, W C Peul Fuente: Traducción y resumen objetivo: Dra. Marta Papponetti. Especialista en Medicina Interna. Diagnosis and treatment of sciatica. BMJ 2007;334;1313-1317*)

Instalife to treat sciatica pain (Justification))

Instalife is a non-invasive medical device for the treatment of pain associated with sciatica that is placed below the knee of the affected leg for two hours a day. The device via a rigid plate causes a moderate pressure on the sciatic nerve preventing or moderating nerve transmission of pain.

The product already has CE marking and market experience to be a safe treatment which only caused some mild skin reactions in patients allergic to neoprene.

Its misuse only causes discomfort without giving rise to other complications.

2.- OBJETIVES OF THE STUDY

The purpose of this clinical study is to evaluate the efficacy and safety of the device in patients diagnosed Instalife mechanical or simple pain associated with the sciatic nerve in case of lumbago, sciatica and piriformis syndrome.

Primary objectives:

The study evaluates the effectiveness of Instalife on improvement, elimination and / or mitigation of pain associated with sciatic nerve during the 4 weeks of treatment.

Secundary objectives:

The study will evaluate the safety of Instalife in patients in the study assessing the possible adverse reactions occurring during use.

Safety assessment:

The safety assessment will be based on the medical examination of patients during the study to detect potential adverse reactions associated with the use of Instalife. In addition, unexpected adverse events were recorded. See section "Adverse Events" for definition and classification. Based on the excellent safety profile of use in the market and the usability test report in healthy volunteers, the expected response to the use of Instalife is not expected to give rise to different adverse reactions to those already registered.

Effectiveness evaluation:

The following aspects will undergo extensive testing to evaluate the effectiveness of the new device:

- Level of pain reduction based on the initial recognition and subsequent test results of mobility.
- Ergonomics device.
- Level of discomfort after use of the product.
- Level of mobility with the device.

3.- METHOD

Patient selection and study circuit

Being a single-center and close study the selection of volunteers has taken place in the hospital by detecting volunteers capable of participation in the study within the center care units.

After to inform the principal researcher on the cases, they were selected volunteers after explaining the conditions of the study and informed consent to collect in under the established legal conditions.

A first diagnostic scan was performed, after which was provided to volunteer a sample of the product under consideration with the corresponding instructions. It was found that the patient has understood how to use the product.

A visit control 14 days of the start of treatment was performed to assess the improvement and voluntary adherence to treatment.

At 28 days of treatment initiation, an exploration of the volunteer is performed to evaluate the efficacy and safety study of the device.

Study variables

Through a structured questionnaire, we collected the clinical and epidemiological variables.

Of the treatment with Instalife were contemplated the understanding of the instructions for use, the adherence to treatment and the evolution of symptoms and possible adverse effects occurred.

Statistic analysis

We have studied the effectiveness of Instalife in treating pain from sciatica, piriformis syndrome and back pain after use for 4 weeks. We have compared the improvement in voluntary (exploration on days 0, 14 and 28) after use and the possible occurrence of adverse effects during treatment.

We have sought to demonstrate the percentage of volunteers who present objective improvement over the initial symptoms after treatment with Instalife.

Percussion test sciatic nerve and Lasegue test will be performed in patients to determine the initial state of the pathology and pain improvement after treatment with Instalife.

4.- PROCEDURE

4.1.- Inclusion criteria:

The study was performed with a group of 50 volunteers who meet all the following inclusion criteria detailed below:

1. Subjects of both sexes (men and women).
2. Aged between 25 and 65 years
3. Existence of low back pain, sciatica or piriformis simple syndrome.
4. Appropriate cultural level and adequate level of understanding of the clinical study
5. Agree to participate voluntarily in the study and have given their written informed consent

4.2.- Informed consent

Written informed consent for each volunteer has been obtained in accordance with the guidelines of Good Clinical Practice. This signed informed consent will remain with the study records at the center.

They were explained to volunteers history of the proposed study, the risks and benefits and rules of use of the device.

4.3.- Epidemiological characteristics

We included 50 volunteers who serve as study group. The study was conducted for 4 consecutive weeks. There has been a first visit for initial assessment and assignment to study group. The second revision visit was held after two weeks, and a final visit for final assessment was made after the fourth week

4.4.- Clinical Characteristics

There has been medical and demographic information about volunteers in medical history, including age, sex and medical history, including: a history of clinically significant abnormalities of all relevant systems of the body, concurrent diseases, pathological personal history. The antecedents specifically include: disease etiology, risk factors such as alcohol and snuff and consumption of drugs. In addition, a summary of interventional procedures and previous surgical and nonsurgical interventions were recorded.

All volunteers has undergone a complete physical examination focusing on the mobility associated with low back pain, sciatica and piriformis syndrome.

4.5.- Treatment Instalife

The device has been used according to their instructions, previously inspecting the integrity of the device and has explained to each volunteer adequately device features and proper use finally realizing a demonstration for proper placement following steps before and during the initial actuation of the device:

1. Identification of the pressure point of the sciatic nerve after the knee of the affected leg
2. Placement of the device around the calf.
3. Anchors and Velcro fastening.
4. Setting the proper working pressure without causing discomfort or inconvenience.

5.- PLAN ESTADISTICO

The design of the present study was conducted with 50 volunteers, whereas if the proportion of volunteers subjected to treatment with Instalife in which improvement in pain occurs is higher than the proportion bibliographically improvement with placebo treatment, which is 50%, we could determine that using Instalife is beneficial for the treatment of pain associated with sciatic nerve.

Starting, as we have noted, that with placebo treatment 50% improvement is obtained after 4 weeks of treatment, and that exists a previous Usability Test for Instalife (IN-USE TEST UNDER PHYSIOTHERAPIST CONTROL CLINICAL STUDY FOR THE APPRAISAL OF THE CUTANEOUS ACCEPTABILITY OF A MEDICAL DEVICE INVESTIGATIONAL PRODUCT, APPLIED UNDER THE NORMAL CONDITIONS OF USE, FOR 1 WEEKS, IN BOTH SEX ADULT SUBJECTS), which gives us an improvement rate of 80% in two weeks, it is expected to obtain, after the test clinical done within 4 weeks, an improvement of at least 80% of volunteers treated with Instalife.

Thereby, a null hypothesis according to which there is no differences between patients treated with placebo (as source is) and treated with Instalife can be set, and an alternative hypothesis (to demonstrate) in which patients treated with Instalife have a 30% improvement over placebo treatment, waiting, therefore, to reject the null hypothesis will be obtained at least 80% improvement in the study volunteers after using Instalife for 4 weeks

6.- EVALUATION

INCLUSION OF VOLUNTEERS:

The total number of volunteers under the study is 50.

EPIDEMIOLOGICAL FEATURES:

- Male volunteers: 16 (32 %).
- Average age of male volunteers: 48.
- Female volunteers: 34 (68 %).
- Average age of female volunteers: 47.

CLINICAL FEATURES OF VOLUNTEERS:

- Volunteers with Lumbalgia: 16 (32 %)
  - bilateral: 9.
  - right: 4.
  - left: 3.
- Volunteers with Lumbosciatalgia: 32 (64 %)
  - bilateral: 5.
  - right: 17.
  - left:10.
- Volunteers with Piriformis Syndrome: 2 (4%).
  - right: 1
  - left: 1

EVALUATION OF EFFECTIVENESS:

- Level of pain reduction:
  - Improvement of pain in 84.00% of volunteers.
  - No improvement of pain in 16.00% of volunteers.

- Ergonomics device:
  - Suitable design for 84.00% of volunteers.
  - Not suitable design for 16,00 % of volunteers.

- Level of discomfort after use of the device:
  - No discomfort after use in 100,00 % of volunteers.
  - Any discomfort after use in 0,00 % of volunteers.

- Level of mobility after use of the device:
  - Improvement of mobility in 84,00 % of volunteers.
  - Not improvement of mobility in 16,00 % of volunteers.

- Improved in radicular signs:
  - Improved in radicular signs in 84,00 % of volunteers.
  - Not improved in radicular signs in 16,00 % of volunteers.

SAFETY ASSESSMENT - ADVERSE EVENTS:

- Reported by volunteer related to the device:
  - Any adverse effect in 0,00 % of volunteers.
  - No adverse effects in 100.00 % of volunteers.

- Reported by volunteer related to the procedure:
  - Any adverse effect in 0,00 % of volunteers.
  - No adverse effects in 100.00 % of volunteers.

- Observed by researcher related to the device:
  - Any adverse effect in 0,00 % of volunteers.
  - No adverse effects in 100.00 % of volunteers.

- Observed by researcher related to the procedure:
  - Any adverse effect in 0,00 % of volunteers.
  - No adverse effects in 100.00 % of volunteers.

LEVEL OF ABANDONMENT IN THE TREATMENT:

- Abandonment of treatment in 0,00 % of volunteers.
- No treatment abandonment in 100,0 % of volunteers.

SATISFACTION AFTER TREATMENT:

- Fully satisfied in 84,00 % of volunteers.

- Fully unsatisfied in 16,00 % of volunteers.

7.- DISCUSSION

During the course of the study there has been any volunteer who has left the treatment which, according to the conditions of the trial protocol, the sample is considered representative and the study results obtained after evaluating the data are also considered objectives, confirming an improvement of over 80% mechanical or simple pain associated with back pain, sciatica and piriformis syndrome, suffered by volunteers

During this period of study, volunteers were not subjected to any other treatment that could mask the effects provided by the device used.

Determining the improvement of symptoms was verified by medical staff after assessing the level of pain reduction, the level of improvement in mobility and the improvement of radicular signs obtained after the exploration of volunteers at the end of the study compared to the initial state thereof.

On the other hand, note that during the course of the study, have not appeared trouble of placing the device or adverse reactions in any of the volunteers, notified by them or observed by investigators.

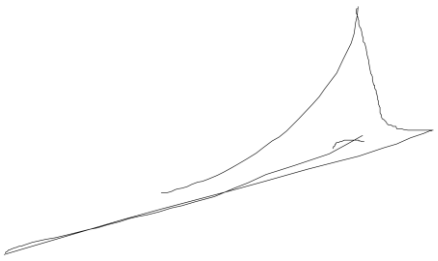
8.- CONCLUSIONS

- It is considered that the device has obtained a rate of improvement of mechanical or simple pain associated with back pain, sciatica and piriformis syndrome in 84%, 50% higher than that obtained when using treatments with placebos, and improvement values similar to other therapeutic alternatives on the market
- The improvement of symptoms was higher in volunteers affected piriformis syndrome, having been achieved in 100% of them, followed by improvements of 90.60% achieved in the volunteers with sciatica and 68.75% in volunteers with lumbalgia.

- There is a slight variation, not relevant, in the results related to the sex of the volunteers, as the percentage of men who have obtained beneficial effects following treatment with Instalife application has been of 93.75%, slightly greater than 82.35% of women treated, reversing the trend among volunteers who have not had improvement being in this case the higher percentage among women stands at 17.65% compared with 6.25% of men.

- The conclusion is that the objectives of the study for the improvement of symptoms of volunteers with mechanical or simple pain associated with the sciatic nerve in cases of low back pain, sciatica or piriformis syndrome have been reached, being achieved in 84% of the volunteers studied, with a level of satisfaction also of 84%, with an evaluation of the appropriate design of the device of 84% of volunteers and a safety assessment for use of 100% by not having appeared adverse events in any volunteer, so it is considered that Instalife device is effective in treating such mechanical or simple pain.

Seville, December 23th 2015.



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