The Using of Neurocryostimulation in Military Ankle Sprains (TUNEMAS)

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Sponsor:

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ClinicalTrials.gov Identifier:

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History of Changes

Purpose

Introduction: The military population is at high-risk for injury with by painful sprains, especially of the ankle. The referenced treatment method for pain is the cryotherapy, consisting in applying cold-packs to the injured ankle several times a day. However, another pain treatment has been developed and is commonly used by high-level sports teams and rheumatologists but its efficacy has never been assessed within a military population, i.e. the hyperbaric CO2 cryotherapy, also called the neurocryostimulation.

Research design: This study was carried out on a French multicenter basis, the study consisting in a randomized controlled superiority trial and open-label prospective analysis in the treatment of 40-year-old military patients or younger suffering from acute ankle sprains. Two groups were made: patients were treated either by neurocryostimulation or by the referenced cryotherapy (cold-packs). The care protocol for both groups consisted in six supervised 30 minute-sessions within a period of three consecutive days.

Hypothesis: Neurocryostimulation is more effective in the treatment of pain severity resulting from an ankle sprain than the referenced treatment by cold-packs. Moreover, we theorized that the total consumption of paracetamol and the number of days of temporary inaptitude and of work exemption were lower in patients treated by neurocryostimulation.

Outcomes:

For each session, pain severity is assessed on a 100-mm Visual Analog Scale at the beginning and at the end of session 20 minutes later after a four-step walk.

Condition	Intervention
Sprain of Lateral Ligament of Ankle Joint	Device: neurocryostimulation with cryo device Device: cryotherapy with Cold pack® or ice-cubes pack

Study Type:	Interventional
Study Design:	Allocation: Randomized Endpoint Classification: Efficacy Study Intervention Model: Parallel Assignment Masking: Open Label Primary Purpose: Treatment
Official Title:	COMPARAISON D'EFFICACITÉ ENTRE LA CRYOTHÉRAPIE GAZEUSE HYPERBARE ET LA CRYOTHÉRAPIE CONVENTIONNELLE DANS LE TRAITEMENT DES ENTORSES EXTERNESDE LA CHEVILLE Étude randomisée auprès d'Une Population de Militaires

Further study details as provided by Direction Centrale du Service de Santé des Armées:

Primary Outcome Measures:

- Evolution of pain assassed by Visual analogic scale of pain [Time Frame: 2 times in the morning, 2 times in the evening, 3 days long] [Designated as safety issue: Yes]pain is assessed with Visual analogic scale of pain just before the application of cryotherapy (T0) and 20 minutes after the application of cold(T20) right after the patient has taken four-step walk.

Secondary Outcome Measures:

- Daily consumption of paracetamol [Time Frame: every day during 3 days]

[Designated as safety issue: Yes]The daily analgesic consumption (grams of paracetamol) is also reported in medical records every evening by means of doctor-patient interrogation.

Other Outcome Measures:

- number of days of temporary incapacity of work [Time Frame: participants will be followed for the duration of the symptoms (pain, oedema), an expected average of 4 weeks]
  [Designated as safety issue: Yes]The patient must visit the investigator of his center every week, who judges the patient's aptitude to go back to work without any restriction. The investigator will report the total number of days of all temporary inaptitude related to the ankle sprain.
- number of days of work exemption [Time Frame: participants will be followed for the duration of the symptoms (pain, oedema), an expected average of 2 weeks]
  [Designated as safety issue: Yes]The investigator will report,if any, the total number of days of work exempt consecutive to the ankle sprain.

Estimated Enrollment:	190
Study Start Date:	September 2011
Estimated Study Completion Date:	July 2014
Estimated Primary Completion Date:	July 2013 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: cryotherapy using Cold pack® patients with lateral ankle sprain who have been randomized in the "cold packs®" group. Application of cryotherapy with Cold pack® or ice-cubes pack in the sprained ankle during 20 minutes 4 times a day, 3 days long.	Device: cryotherapy with Cold pack® or ice-cubes pack Patients receive 2 controlled applications a day (one in the morning and one in the evening) of cryotherapy with Cold pack® or ice-cubes pack (with average dimensions of 5 cm by 8 cm) to the injury site for a duration of 20 minutes. Furthermore, the patients are instructed to do 2 more applications of the ice-pack during the daytime to follow the usual recommendations. The first and last sessions of each day must be supervised by the medical care Unit to insure standardized data collection for each group.
Active Comparator: cryotherapy using Neurocryostimulation Patient with lateral ankle sprain randomized in the "neurocryostimulation" group. Application of neurocryostimulation with cryo device during 1 minute on the sprained ankle, 2 times a day, 3 days long	Device: neurocryostimulation with cryo device organized in the morning and in the evening during 3days. The gaz is sprayed with cryo device on dry skin over the ankle using a slow, regular, sweeping movement. The tip of the nozzle is kept 15 to 20 cm away from the skin. Neurocryostimulation is applied to patients for a duration of one minute by a trained staff Other Names: • hyperbaric gazeous cryotherapy • neurocryostimulation

Detailed Description:

In France, there is one ankle sprain per 10,000 person/day mainly as a result of athletic practice. The military population is one of the most physically active populations due to taking part in sports exercise, scheduled sports periods and leisure sports , or required military exercise which increase the soldiers' risk for injury to the lower extremity, especially the ankle. The incidence rate for ankle sprain injuries among all -active-duty US service members was 34.95 per 1000 person/year , thus more than 5 times greater than previously reported in civilian studies reported in the literature. These are among the two first leading causes of sports and physical training related hospitalizations among the U.S. Army population.

Sprains can lead to numerous consequences in the long-term in physical restrictions such as, ankle instability, risk of recurrence, but also absenteeism from work and/or participation in sports and chronic pain. A more efficient treatment seems to be necessary in preventing such troubles.

The usual care protocol for ankle sprains (RICE protocol) involve the cryotherapy (usually a cold-pack (R) applied directly to the injury several times a day with no existing undesirable effects).

An innovative treatment method, the neurocryostimulation, developed by Cluzeau and a French Company in 1993, gained rapid and wide-spread use among physiotherapists, rheumatologists, and athletes.It would provide a powerfull anti-inflammatory, myorelaxant and analgesic effect but contradictory results are shown in literature. Demoulin et al. aimed to assess the efficacy of neurocryostimulation following total knee arthroplasty compared to routinely used strategies for applying cold therapy, but didn't show significant differences regarding pain severity, mobility and perimetric measures. However, a pilot study led in Switzerland, comparing the pain reported by patients after an acute post-operative knee arthroscopy, has shown a pain differential higher in the neurocryostimulation than in the referenced cryotherapy (2.2 versus 0.5). And, Chatap et al. showed in a prospective study that pain scores decreased significantly after four sessions in elderly patients with acute or chronic pain.

At this day, No study has proved the efficacy of neurocryostimulation versus cold packs in pain resulting from an ankle sprain . A better treatment of the ankle sprain could reduce pain and , in the same time, also reduce the consumption of analgesics, the time of temporary inaptitudes and of work exemptions.

Eligibility

Ages Eligible for Study:	18 Years to 40 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

age equal or less than 40 years-old, military subject, acute ankle injury, To have completed and signed the informed consent.

Exclusion Criteria:

contraindications to cryotherapy (cold allergy, cryoglobulinemia, Raynaud's phenomenon, cutaneous sensory abnormalities, and diabetes mellitus), paracetamol allergy, 4th grade sprains according to the Trevino Classification (with bone wrenching), to take analgesic or anti-inflammatory treatment other than paracetamol.