Dr. Giuliano De Carolis, CF: DCRGLN66C04F100D, Order of doctors Lucca registration n. 2413

INFORMATION AND INFORMED CONSENT FOR THE ELECTRIC NEUROMODULATION PROCEDURE (PULSED RADIOFREQUENCY) FOR ANALGESIC PURPOSES

INFORMATION SECTION

What is it and what is it for? How is it done?
The procedure consists in positioning a needle-electrode in particular target areas (facet joints, sacroiliac joints, peripheral nerves, painful areas, etc.). This needle-electrode, once correctly positioned, is connected to a device capable of generating pulsed radiofrequency pulses and transmitting them to the tip of the needle-electrode. The effects produced by these impulses on the tissues adjacent to the needle tip are:
1) Generation of heat;
2) Formation of an electric field.
In the case of pulsed radiofrequency, the generation of heat does not exceed 42 ° C so as not to create thermal and irreversible lesions on the tissues near the tip of the needle, while the electric field that is generated creates a stunning of the nerve cells, which is the main mechanism for breaking the vicious cycle underlying chronic pain.

The steps of the procedure:
1) If necessary, the patient is monitored (BP, HR, SaO2) and placed in a suitable position on the X-ray table. The procedure is performed under strict radiological or ultrasound control to allow correct positioning of the needle close to the nerve structure to be treated. The exact positioning of the needle-electrode will be further verified with the use of special electrical stimulations, both sensory and motor.
2) If necessary, a light local anesthesia can be performed at the point of introduction of the needle. On the other hand, anesthesia will not be practiced at the time of stimulation because it is necessary for the patient to report any abnormal painful sensations. In fact, the stimulation will cause on site only a slight sensation of heat and / or tingling.
3) On the day of the block, the patient must continue his normal drug therapy. Important: patients on anticoagulant and / or antiplatelet therapy must notify the doctor in order to proceed with a suspension of therapy or its replacement if deemed necessary.

What are the risks and complications?
Complications could be:
- a transient reduction in the sensitivity of the limbs with transient motor impediment;
- a transient pain in the area where the needle is positioned;
- hematoma at the puncture site;

- local infection;
- accidental puncture of the dura mater (in case of peridural, spinal accesses);
- raised or lowered blood pressure;
- changes in sensitivity in the distribution areas of the nerve subjected to pulsed radiofrequency;
- motor disturbances;
- the risks of allergies, even serious ones, due to the injected substances (you must communicate any allergies to drugs or other substances in a preventive manner);
- the risk of joint or injection site infections (very rare as sterile material is used and all requirements for effective disinfection are observed);
- the possibility of vaso-vagal nervous reactions as a consequence of joint distension or hypersensitivity to the vision of the needles;
- since the procedure is performed under X-ray guidance, possible damage from radiation in particular if the procedure is performed in a female patient of childbearing age with an unknown pregnancy status;
- since the response to medical treatments is necessarily individual, it is not possible to guarantee any a priori results.

Possible alternatives to the procedure
The patient can however freely decide not to undergo any recommended procedure and to continue with any pharmacological, rehabilitative or other treatments.

What are the consequences of not having the recommended health treatment?
There are no real risks associated with "Not Undergoing" the procedure, but a possible therapeutic option is renounced.

After the treatment
In the 48 hours following the treatment it is recommended to rest from work activities. In case of impaired ability to react it is also recommended not to drive cars or other vehicles, not to use electric tools or to operate machinery.
The neuro modulation procedure carried out could give a possible and expected transitory worsening of the painful symptoms in the first week and beyond. If necessary, the patient can 'take additional therapy of pain relievers as needed that she usually uses.

FURTHER NOTES FROM THE PRINCIPAL DOCTOR:

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FORM TO BE READ CAREFULLY BEFORE SIGNING INFORMED CONSENT
and return to the doctor on the day of admission for the planned procedure.

Delivery date of the delivery information form

PERSONAL SECTION AND CONSENT

I, the undersigned (name) .....(last name) ……

Born in the……..…… resident in ... .

If necessary
Legal representative of …… ..... born in the ……

I declare that:
have read the information section,
have had the opportunity to request further information from the doctor,
having well understood the explanations that have been provided to me, the nature, purpose, benefits, any alternatives and any risks of the intervention,
having been informed of the negative health consequences to which I would expose myself by not undergoing the recommended surgery and therefore I agree to undergo it
having been informed that I can withdraw my consent at any time.

SECTION TO BE COMPLETED ONLY IN CASE OF DISSENT
I declare that:
have read the information section,
have had the opportunity to request further information from the doctor,
have well understood the explanations that have been provided to me, the nature, purpose, benefits, possible alternatives and possible risks of this intervention and the complications that may derive from it,
having been informed of the consequences to which I would expose myself by not undergoing the recommended surgery and therefore I DO NOT agree to undergo it. In fact, I expressly and consciously declare that I do not want to accept the risk of the negative consequences on my health that could derive from it, preferring instead to expose myself to the risk of the negative consequences deriving from failure to carry out the recommended health treatment,
having been informed that I can revoke the dissent at any time.

Signed on …… / …… / ……

Signature of patient or legal representative .... ……

If necessary: I declare that I am / not pregnant ....

Signature and stamp of Doctor Giuliano De Carolis ……..