

**PROJECT: "VISCERAL RESERVE FAT LIPOLYSIS USING TECARTHERAPY: ANTHROPOMETRIC, BIOCHEMICAL AND MRI IMAGING STUDY."**

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Dear participant:

First, thank you for participating in this research, which aims to understand the effect of high-power resistive capacitive radiofrequency in treating visceral fat.

We will evaluate the role of radiofrequency in reducing body fat and changes in biochemical markers linked to inflammation. Additionally, we will evaluate the impact of quality of life before and after radiofrequency treatment through questionnaires.

We want to ask you if you suffer or have:

(INCLUSION CRITERIA): **Based on what criteria you can be included in the study.**

To answer for the **patient**:

1. Is the Patient healthy

<input type="checkbox"/>	Yes
<input type="checkbox"/>	No

2. The patient's age is between 20 and 60 years.

<input type="checkbox"/>	Yes
<input type="checkbox"/>	No

(EXCLUSION CRITERIA): **Based on what criteria you can be excluded from the study.**

To be answered by the **patient**:

- 1- If you have a contraindication to the use of radiofrequency such as pregnancy, metal prostheses, active bacterial infection, malignant neoplasia, pacemaker or battery-operated devices.

<input type="checkbox"/>	Yes
<input type="checkbox"/>	No

2- If you have active neoplasia within 5 years:

<input type="checkbox"/>	Yes
<input type="checkbox"/>	No

3- If you have diabetes or another metabolic disease:

<input type="checkbox"/>	Yes
<input type="checkbox"/>	No

**What type of treatment will be performed:**

When applying radiofrequency, water and electrically charged proteins will move when an electromagnetic field is applied from the positive pole to the negative pole. This will stimulate the destruction of adipose cells throughout the treated area and gradually eliminate lipids through the lymphatic system, which reduces the volume of the tissue.

This will be confirmed by the questionnaires and the tests, which will be carried out before starting the treatment, and at the end of it.

Radiofrequency is a safe and well-tolerated treatment. You will only feel a slight local increase in temperature. If you feel discomfort or discomfort, you can notify the specialist or disconnect the equipment with the safety control that you will have in your hand.

The duration of the treatment will be 80 minutes daily, resting on the weekend, a total of 10 sessions will be performed within 2 weeks.

**What technology will be used:**

The treatment will be performed with TECAR EVOLUTION technology from CAPENERGY Medical, with its "C" range equipment, such as radiofrequency diathermy electro-medicine devices conducted using contact electrodes in compliance with the ISO 13485 health regulations with CE MEDICO marking with the provision of own national and international patents.

<https://capenergy.com/es/productos/>

**Treatment Location:**

**Clínica INNEOTERAPIA LES CORTS**  
c/ Bordeus, 2-4  
08029 – Barcelona  
Telephone: + 34 687.452.613  
Email – [fisio@capenergy.com](mailto:fisio@capenergy.com)

**Clínica INNEOTERAPIA DESPI**  
c/ Jacint Verdaguer, 4  
08970 – Sant Joan Despi  
Telephone: + 34 627.331.078  
Email – [fisio@capenergy.com](mailto:fisio@capenergy.com)

**What commitments must you assume if you participate:**

If you are willing to undergo the treatment, you must commit to the following aspects:

- 1- Sign the informed consent and other study documentation
- 2- Perform MRI and biochemical analysis at the beginning and end of treatment
- 3- Transfer the data of the treatment sessions.

The participant must be able to withdraw at any time, without giving explanations and without causing any harm, although the treatment will not end.

**Requirements:**

- ✓ Come to the session in comfortable clothing.
- ✓ Be punctual at the appointed time.

**ARSOPOL data protection rights.**

ARSOPOL rights (Access, Rectification, Cancellation and Opposition) are regulated by Organic Law 3/2018 on Data Protection and Guarantee of Digital Rights.

The data will be processed for explicit and legitimate research purposes only and will not be further processed in a manner incompatible with the mentioned purposes. The data will only be kept and processed for two years, then it will be deleted.

According to Organic Law 3/2018 on data protection, you can, at any time, exercise before the person responsible for the treatment your rights of access, rectification, opposition, deletion, limitation of treatment, and portability and not be subject to individualized decisions. Requests will be responded to within one month.

Custody and compliance with the LOPD correspond to CAPENERGY MEDICAL, SL with CIF B-62171731, located at c/ Marie Curie, 22 – 08970 – Sant Joan Despi (Barcelona) – email: info@capenergy.com.

Participants have the Right to Information regarding the use of data by providing their consent in an attached document.

The person responsible for the research is **Dr. JESÚS RODRÍGUEZ LASTRA**, telephone number (+34) 603.648.880 – email: clinicalsupport@capenergy.com

We are happy to clarify any doubts, concerns or questions that may arise during the investigation. You can request to speak with any of us by phone: at 687 45 26 13 or write your questions by email to any of the researchers.

**What will be done with the data:**

The data obtained from carrying out the treatments, which may include measurements and graphic testimonies, will be processed for explicit and legitimate research purposes only and will not be further processed in a manner incompatible with the mentioned purposes.

The data will only be maintained and processed for two years and then will be deleted in compliance with legislation 41/2002 of November 14, safeguarding the data in the CAPENERGY Medical facilities.

As established by the General Data Protection Regulation and Organic Law 3/2018 on Data Protection and Guarantee of Digital Rights, the participant may, at any time, exercise their rights of access, rectification, and opposition before the data controller, deletion, limitation of treatment, portability and not being subject to individualized decisions.

Requests will be responded to within one month.

We thank you for your full participation in this study and for signing ANNEX 3 as a sign of agreement with the terms expressed in this project.

This document is accompanied by the following ANNEXES documents:

- ANNEX 1 - EXERCISE OF THE RIGHT OF ACCESS TO PERSONAL DATA
- ANNEX 2 – INFORMED CONSENT

**ANNEX 1 - EXERCISE OF THE RIGHT OF ACCESS TO PERSONAL DATA**

RESPONSIBLE FOR THE TREATMENT: Jesús Rodríguez Lastra, with Address at Carrer Marie Curie, 22 – 08970 – Sant Joan Despi

**DATA OF THE PARTICIPANT OR LEGAL REPRESENTATIVE.**

Mr./ Mrs. ...., of legal age, residing in (locality) ..... with DNI....., through this document you exercise the right of access to my data, following the provisions of article 15 of the EU Regulation 2016/679, General Data Protection (RGPD).

**REQUEST**

That the right of access be provided free of charge by that person responsible within one month from receipt of this request, and that the following information be sent to the address indicated above:

- ✓ Copy of my personal data that is processed by the person responsible.
- ✓ The purposes of the treatment, as well as the categories of personal data processed.
- ✓ The recipients or categories of recipients to whom my personal data have been communicated, or will be communicated, including, where appropriate, recipients in third parties or international organizations.
- ✓ Information about the appropriate safeguards regarding the transfer of my data to a third country or an international organization, where applicable.
- ✓ The expected conservation period, or if this is not possible, the criteria to determine this period.
- ✓ If there are automated decisions, including profiles, significant information about the logic applied, as well as the importance and anticipated consequences of the mentioned treatment.
- ✓ If my personal data has not been obtained directly from me, the information available about its origin.
- ✓ The existence of the right to request rectification, deletion or limitation of the processing of my personal data, or to oppose such processing.
- ✓ The right to file a claim with a supervisory authority.

In accordance with the provisions of article 13 of the European Data Protection Regulation (GDPR), I have been informed by Capenergy Medical SL:

- ✓ That my personal data will be used for Research and Commercial Dissemination purposes.
- ✓ That the person responsible for the treatment and custody of all data, photographs and videos is CAPENERGY MEDICAL, SL with CIF B-621717131, located at c/ Marie Curie, 22 -08970 Sant Joan Despi - Email info@capenergy.com
- ✓ That CAPENERGY MEDICAL, SL will not transfer my personal data to third parties or other recipients, and that my data will not be subject to international transfer.
- ✓ That my data will be kept indefinitely and confidentially.
- ✓ That I can exercise the rights of access, rectification, deletion, opposition and limitation of processing by request addressed to CAPENERGY MEDICAL, SL

- ✓ Likewise, I can submit claims to the Catalan Dades Protection Authority ([apdcat.gencat.cat/ca/inici/](http://apdcat.gencat.cat/ca/inici/)) and make any queries I consider necessary to CAPENERGY MEDICAL, SL.

That I can make any queries and complaints in writing through email at [info@capenergy.com](mailto:info@capenergy.com) or by telephone contact at + 34 687452612.

**ANNEX 2 - INFORMED CONSENT**

**PROJECT:** "VISCERAL RESERVE FAT LIPOLYSIS USING TECARTHERAPY: ANTHROPOMETRIC, BIOCHEMICAL AND MRI IMAGING STUDY"

Mr./ Mrs. ...., of legal age, residing at (address) .....  
 ..... no. ...., of the town of ..  
 ..... Province ..... C.P....., with  
 D.N.I....., email ..... Through the present writing

**I DECLARE**

That I have read the Study Project Information Sheet that has been given to me and Annexes 1 and 2 that accompany the mentioned documentation.

That I have been able to ask the questions and doubts that have arisen in this regard and that I have received sufficient information from Mr./Mrs....., who explained to me all the details, in particular:

- ✓ That my participation is completely voluntary
- ✓ The purpose of the study for which I consent.
- ✓ The benefits expected from it are beneficial to my health.
- ✓ Possible inconveniences linked to the study, including the possibility of being contacted later to collect new data.
- ✓ The identity of the person responsible for the study, Jesús Rodríguez Lastra, a doctor from the University of Carabobo Valencia, Venezuela.
- ✓ My right to revoke this consent and its effects, including the possibility of deletion of the sample and the fact that these effects will not extend to the data resulting from the studies that have been carried out.
- ✓ The guarantee of confidentiality that has been given to me regarding the information obtained, and the identity of the people who will have access to my personal data.
- ✓ The possibility of exercising the rights recognized by the European Data Protection Regulation (GDPR)

• I do not want to have access to the results nor do I want to be informed about it, which is why, in the event of possible harm to me, I request that it be communicated to me.

Likewise, in accordance with article 7 of Law 14/2007, of July 3, on biomedical research, participation in the study implies the renunciation by the participants of any right of an economic or other nature over the results that may be derived directly or indirectly from the research, therefore, sign as a sign of agreement with all the terms outlined in this document.

Patient's Signature:

Researcher's Signature:

Name & Surname:

Name & Surname:

Date:

Date:

This document will be signed in duplicate. The researcher will keep one copy and the participant the other.