

**EudraCT number: 2018-000201-24**

**Title: Effectiveness and cost-effectiveness of Ozone therapy in patients with ischemic heart disease refractory to medical and surgical treatment: Randomized, triple-blind clinical trial.**

**Main Objectives of the Trial**

- 1) To assess the clinical effect and impact on self-perceived health-related quality of life (HRQOL) by addition of Ozone therapy to the standard management of patients with heart failure refractory to medical and surgical treatment.
- 2) To estimate additional cost and the ratio of cost-effectiveness of adding Ozone therapy to standard treatment.

**The trial has prematurely ended.**

**Reasons:**

- A very low recruitment.
- For three years, they were submitted three potential patients to evaluate inclusion in the trial, and only one could be finally enrolled.
- On 30/November/2020 the trial was prematurely ended
- On 15/December/2020 this decision was notified to the Spanish Regulatory Agency (AEMPS) and the Ethics Committee.

**Results:**

- With only one patient enrolled in the trial any conclusion could be obtained.

Below is a summary of the data obtained in this patient related to the two most relevant variables. The summary include data from the trial (inside the assigned placebo group) and from the further compassionated treatment after trial ended.

**6 minute walk distance**

- Before placebo treatment (oxygen group) in the trial: 324 m
- After placebo treatment (oxygen group) in the trial and before compassionated treatment with ozone (after trial ended): 288 m
- After compassionated treatment with ozone (after trial ended): 450 m

**Minnesota Living with Heart Failure Questionnaire -MLHFQ- (higher is worst):**

- Before / after placebo treatment (oxygen) in the trial: 59 / 61
- Before / after compassionated with ozone (after trial ended): 89 / 59

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