

PUBLIC REALEASE
Ozone Therapy, COVID-19, Pseudo-therapy, Judicial Decision
Madrid, August 16, 2021

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Judicial Decision

There have been recent media reports resulting from an order issued by Judge Carola Soria Piquer, of the Appellate Administrative Court No. 1 of Castellón de la Plana (order 158/2021, August 13, 2021) authorizing the application of ozone therapy to a patient "as his life was in serious danger and the treatments rendered to date in the ICU of La Plana Hospital had not had a positive effect".

Official Position of the Ministry of Universal & Public Health, Generalitat Valenciana

According to the public information available, the ministry has denied ozone therapy for the following reasons: (a) It was not approved by the AEMPS [For its acronym in Spanish: Spanish Agency for Medicines and Health Products]. (b) The Ministry of Health issued a statement in November of 2020, indicating ozone is not approved for use as a biocide in patients. (c) Ozone therapy was not within the portfolio of services of the Valencian Community Health System. (d) Ozone therapy is a pseudoscience since there is no scientific evidence to support it.¹

Entities against the judicial decision

As a result of the court decision, the Hospital Board of the Hospital Universitario de la Plana,² the Castellón Medical Association (COMCAS),³ the Valencian Society of Critical Intensive Medicine and Coronary Units (SOVAMICYUC),⁴ the Spanish Society of Emergency Medicine,⁵ and the Association to Protect the Sick from Pseudoscientific Therapies (APETP)⁶ publicly spoke out against the decision.

¹ <https://www.elmundo.es/comunidad-valenciana/castellon/2021/08/06/610c21d4fc6c8305418b45b9.html>
<https://www.elperiodicomediterraneo.com/vilareal/2021/08/06/sanitat-aplicara-ozono-paciente-hospital-55964045.html>
https://www.elperiodic.com/burriana/grito-desesperado-familia-burriana-enfermo-critico-covid-plana_764259
https://www.elperiodic.com/burriana/hospital-plana-acata-orden-judicial-permitira-ozonoterapia-paciente-critico-covid_765102
<https://elpais.com/sociedad/2021-08-13/los-medicos-de-las-uci-criticaron-el-uso-compasivo-de-la-ozonoterapia-en-un-enfermo-de-covid-de-un-hospital-valenciano.htm>

² https://www.lespanol.com/alicante/20210814/medicos-valencianos-guerra-imponer-pseudoterapia-tratar-covid/604190077_0.html

³ <https://www.comcas.es/blog/sala-de-prensa-3/post/el-comcas-apoya-a-los-profesionales-del-hospital-la-plana-1221>

⁴ <https://sovamicyuc.es/el-ozono-en-estos-momentos-no-se-contempla-como-una-alternativa-segura-y-eficaz-para-pacientes-afectos-de-covid-19/>

⁵ https://www.lespanol.com/alicante/20210814/medicos-valencianos-guerra-imponer-pseudoterapia-tratar-covid/604190077_0.html

⁶ <https://www.apetp.com/index.php/2021/08/13/comunicado-sobre-la-aplicacion-de-ozonoterapia-en-pacientes-de-covid-19/>

AEPRIMO's Position

Taking into account the above, AEPRIMO [For its acronym in Spanish: Spanish Association of Medical Professionals in Ozone Therapy] respectfully states the following:

1.- Medical Act. "Ozone therapy is a *medical act* and should be practiced by medical doctors and implemented with scientific rigor." ⁷ Auxiliary health personnel must work under the direct supervision and responsibility of a doctor.

2.- Ozone generators. Medical ozone generators are medical devices classified as a IIb medical device and must have the CE corresponding marking. ⁸

3.- It is not pseudo-therapy. Ozone therapy has not been classified as pseudo-therapy by the Spanish government, nor has it been defined as such. There is no mention in the documents of November 2018, "Plan for the Protection of Health against Pseudotherapies", ⁹ nor does the document "Context and evaluability analysis: Exploratory analysis of systematic reviews and clinical trials published in Pubmed (2012-2018)" ¹⁰ mention of ozone therapy as a pseudo-science. This means that the government does not define ozone treatment as a pseudo-therapy.

4.- Pro-drug. Medicinal ozone is a pro-drug, since it is a gas that does not follow the pharmacokinetics and pharmacodynamics of a drug. At the meeting of January 23, 2019 between AEPRIMO and the AEMPS, its director, María Jesús Lamas Díaz pointed out that ozone could not be classified as a medicine since it does not act on cell receptors, which it is a fundamental property that defines medicines. It is also not a medical device. For this reason, the AEMPS, which was created to regulate medicines and health products, was not the entity to rule on ozone therapy since it did not fall within the scope of its authority. Director Diaz indicated that ozone therapy should be considered a medical technology.

Consequently, and in accordance with the provisions of the AEMPS, ozone therapy should be considered as a health technology, in the same class, for example, as hyperbaric therapy, radiotherapy, magnetotherapy, laser therapy, etc.

5.- Ozone therapy in public hospitals. In Spain, there is evidence that ozone therapy is practiced for pain and diabetic foot management in 20 public hospitals. Two of these hospitals are in the Valencian Community. ¹¹ See annex I.

⁷ Madrid Declaration on Ozone Therapy, ISCO3, 3^a. ed., 2020, ítem 5. World reference document for the practice of ozone therapy, translated into nine languages. <https://isco3.org/>

⁸ Guidelines and Recommendations for Medical Professionals Planning to Acquire a Medical Ozone Generator. <https://isco3.org/wp-content/uploads/2015/09/Generadores-ISCO3-SOP-DEV-01-01-2019-CORREGIDA-1.pdf>

⁹ <https://www.mscbs.gob.es/gabinetePrensa/notaPrensa/pdf/20181141118135247771.pdf>

¹⁰ <https://www.cofpv.org/doc/evaluabilidad-pseudoterapias-informate.pdf>

¹¹ Positioning of the Spanish Society of Pain against Ozone Therapy in the Treatment of Pain. SED [For its acronym in Spanish.

6.- Ozone therapy and scientific foundations. The Hospital Board of the Hospital Universitario de la Plana and SOVAMICYUC say that "the studies published with the use of this 'biocide' are studies of low scientific significance and in no cases were the treated patients were in critical condition". The APETP affirms that ozone therapy studies "are generally of low quality, with a small number of patients and without statistical significance. They are a constant in the world of pseudotherapies (...) there must be a clinical trial where these questions are answered."

We cordially invite you to consult the following research published in PubMed that refutes the above statement:

- a) *"Complementary application of the ozonized saline solution in mild and severe patients with pneumonia COVID-19: A non-randomized pilot study."* J Pharm Pharmacogn Res 9(2): 126–142. Schwartz, A.; Martínez-Sánchez, G.; de Lucía, A. M.; Viana, S. M.; Constanta, A. M.¹² **A study based on the results obtained in the middle of the pandemic at the Viamed Virgen de la Paloma Hospital in Madrid (Spain). During the work carried out, about 600 treatments with Ozonized Saline Solution were provided, including cases of ICU. We believe that it is an important example of cases to consider.**
- b) *"Potential Cytoprotective Activity of Ozone Therapy in SARS-CoV-2/COVID-19"* Antioxidant Journal. Impact level 5,014.
Gregorio Martínez-Sánchez, Adriana Schwartz, Vincenzo Di Donna.¹³
- c) *"Ozone therapy for patients with COVID-19 pneumonia: Preliminary report of a prospective case-control study"*. Alberto Hernández, Montserrat Viñals, Asunción Pablos, Francisco Vilás, Peter J Papadakos, Duminda N Wijesundera, Sergio D Bergese, Marc Vives. Int Immunopharmacology 2021, 90: 10726. Clinical trial registration number: NCT04444531. Impact level 3.943.¹⁴
- d) *"Safety and efficacy of ozone therapy in mild to moderate COVID-19 patients: A phase I/II randomized control trial (SEOT study)"*. Mili Shah, Jignasha Captain, Vidyadhar Vaidya, Arvind Kulkarni, Kedar Valsangkar, Pradeep M K Nair, Gayatri Ganu. Int Immunopharmacol 2020 Dec 23;91:107301. doi:

Spanish Society of Pain). Document submitted to the OMC [For its acronym in Spanish. Collegiate Medical Organization) on December 20, 2018.

¹² <https://pubmed.ncbi.nlm.nih.gov/32384798/>

Este estudio se encuentra en la Biblioteca virtual de la OMS:

<https://search.bvsalud.org/global-literature-on-novel-coronavirus-2019-ncov/resource/en/covidwho-854062>

¹³ <https://pubmed.ncbi.nlm.nih.gov/32384798/>

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¹⁴ <https://pubmed.ncbi.nlm.nih.gov/32384798/>

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- 10.1016/j.intimp.2020.107301. Impact level 3.943. ¹⁵
- e) “*Coronavirus-19 mild to moderate pneumonia Management with blood Ozonization in patients with Respiratory failure (CORMOR) multicentric prospective randomized clinical trial.*” Emanuela Sozio, Amato De Monte, Giovanni Sermann, Flavio Bassi, Davide Sacchet , Francesco Sbrana , Andrea Ripoli, Francesco Curcio, Martina Fabris , Stefania Marengo, Daniele Italiani, Daniela Luciana Boccalatte-Rosa, Carlo Tascini , CORMOR study Group. Int Immunopharmacol. 2021 Jun 12;98:107874. doi:10.1016/j.intimp.2021.107874. Impact level 3.943. ¹⁶
- f) “*Oxygen-ozone (O2-O3) immunoceutical therapy for patients with COVID-19. Preliminary evidence reported.*” Marianno Franzini, Luigi Valdenassi, Giovanni Ricevuti, Salvatore Chirumbolo, Markus Depfenhart, Dario Bertossi, Umberto Tirelli. International Immunopharmacology. 2020 August 8, 88: 106879. Impact level 3.380. ¹⁷
- g) “*Blood ozonization in patients with mild to moderate COVID-19 pneumonia: a single centre experience*”. Carlo Tascini, Giovanni Sermann, Alberto Pagotto, Emanuela Sozio, Chiara De Carlo, Alessandro Giacinta, Francesco Sbrana, Andrea Ripoli, Nadia Castaldo, Maria Merelli, Barbara Cadeo, Cristiana Macor, Amato De Monte. Internal and Emergency Medicine. 2020 Nov. 1. Impact level 2.322. ¹⁸

7.- Ozone therapy: complementary therapy. SOVAMICYUC and COMCAS erroneously affirm that ozone therapy "at this time is not considered as a safe and effective alternative therapy in critically ill patients affected by COVID 19."

Ozone therapy is not an "alternative" but a "complementary" therapy that was implemented as such in the study carried out at the Viamed Virgen de la Paloma Hospital in Madrid.

“Ozone therapy is an adjunctive therapy and should be performed *along with* and not *instead of* the allopathic medicine. Understanding the difference between *complementary* and *alternative* is critical.”¹⁹ It is about complementing, not substituting. Covid-19 is a very complex disease in which many different molecules intervene and interact. It is not single mechanism, so it is very difficult for a single drug or agent to have a dramatic effect. That is why neither a single drug nor medical technique could be considered unique, it will be a combination of them that will provide benefits to the patient.

¹⁵ <https://pubmed.ncbi.nlm.nih.gov/33421928/>

¹⁶ <https://pubmed.ncbi.nlm.nih.gov/34186281/>

¹⁷ <https://pubmed.ncbi.nlm.nih.gov/32795898/>

¹⁸ <https://doi.org/10.1007/s11739-020-02542-6>

¹⁹ Madrid Declaration on Ozone Therapy, ISCO3, 3ª. ed., 2020, ítem 1. World reference document for the practice of ozone therapy, translated into nine languages. <https://isco3.org/>

8.- Efficacy and safety. The Board of Directors of the Hospital Universitario de la Plana opposes "unauthorized therapies that have not sufficiently proven their efficacy and safety." And, together with SOVAMICYUC they affirm that ozone "is neither safe nor effective".

The study "Complementary application of the ozonized saline solution in mild and severe patients with pneumonia COVID-19: A non-randomized pilot study." Based on the work by Dr. Schwartz et al at the Hospital Viamed Virgen de la Paloma, and the study "Ozone therapy for patients with COVID-19 pneumonia: Preliminary report of a prospective case-control study." by Dr. Alberto Hernández et al. have both shown that ozone is safe and effective.

While ozone treatments applied in a scientifically correct manner have been demonstrated to be safe and effective, we pose the following corollary question: "Have all the drugs and protocols authorized to treat COVID-19 patients been 'sufficiently' demonstrated to be effective and safe?", During the months of the pandemic, various therapeutic techniques have been employed by entities such as the Hospital Board of the Hospital Universitario de la Plana or the Spanish Society of Emergency Medicine, to treat Covid stating that these techniques, "however, had always been proved to be effective and authorized for use in patients" ²⁰

That's not true. A clear example is in remdesivir, ²¹ where the parameters of efficacy and safety were set using widely lax and insufficient scientific criteria. The FDA on May 1, 2020 authorized remdesivir for the treatment of COVID-19, despite acknowledging that, "it is an investigational drug and is not currently approved for use."

Gilead, the maker of remdesivir, said that it was, "an investigational drug that has not been approved by the FDA for use."

Regarding the side effects, the FDA said that, "remdesivir was still under study so it was possible that all the risks were not known at this time." To this they added, "Serious unexpected side effects can occur."

The European Union, through the Committee for Medical Products for Human Use, made up of experts from the competent authorities of the different EU Member States, including the Spanish AEMPS, recommended on June 25, 2020, that, "a conditional authorization be granted to Veklury (remdesivir), even though it had explicitly stated that remdesivir had, "less than the normally expected data."

²⁰ https://www.elsepanol.com/alicante/20210814/medicos-valencianos-guerra-imponer-pseudoterapia-tratar-covid/604190077_0.html.

²¹ On this point Schwartz, Adriana. (2020). Editorial. Ozone Therapy Global Journal. Vol. 10, nº 1, pp. 7-11. https://ozonetherapyglobaljournal.es/pdfs_num10/ART_1en_FINAL_0_EDITORIAL_2020en.pdf

9.- Application Routes of ozone therapy. Based on the scientific research reviewed by AEPROMO, it considers that Ozonized Saline Solution, Major Autohemotherapy and Rectal Insufflation are, the systemic application routes of ozone therapy, which can be employed as a complementary therapy in COVID-19 patients.

On the other hand, we consider that the "direct intravenous gas" therapy does not have published studies that demonstrate its safety and scientific validity. Direct intravenous therapy does not falls within the recommended administration routes specified in the Madrid Declaration on Ozone Therapy ²² and ISCO3 (International Scientific Committee of Ozone Therapy). ²³ This is one of the reasons why we consider communication between specialized scientific entities and the health important, since this is the only way by which malpractice can be avoided. The only systemic routes of ozone administration that have studies that demonstrate its safety and efficacy are: Ozonized Saline Solution, Major Autohemotherapy, Rectal Insufflation and Minor Autohemotherapy.

Aepromo clearly opposes anyone who goes beyond the boundaries of good medical practice and safety in the application of ozone therapy. We repeat, direct intravenous gas is not a recommended or safe administration route. This is stipulated by the 2020 Madrid Declaration on Ozone Therapy, a document translated into 9 languages and a worldwide reference.

10.- Benefits of the Ozonized Saline Solution. The use of the Ozonized Saline Solution would result in (a) an enormous health benefit for the patients; (b) a reduction in the intense and commendable work carried out by all health personnel, to whom AEPROMO expresses its gratitude and solidarity; and (c) in a significant decrease in the healthcare expenditures, according to the study carried out at the Viamed Virgen de la Paloma hospital in Madrid. Further findings of the study were:

Within 24 hours of applying the Ozone Saline Solution (SSO3), the CRP curves (a maker that measures systemic inflammation) plummeted as did other biochemical markers and clinical symptoms of disease. Body temperature quickly returned to normal, while dyspnea and fatigue significantly subsided.

At 72 hours, the oxygen saturation in all patients had notably improved (towards 96-98%).

On the fifth day of treatment, the basic medications were reduced in most patients and some were discharged with low-risk lab values.

On the tenth day, the entire COVID-19 floor of the hospital employing ozone therapy had been discharged. The medical team did not observe any side effects and no deaths

²² Madrid Declaration on Ozone Therapy, ISCO3, 3ª. ed., 2020, ítem 3.3.1. World reference document for the practice of ozone therapy, translated into nine languages. <https://isco3.org/>

²³ Non-recommended routes of application in ozone therapy. ISCO3, 2017. <https://isco3.org/wp-content/uploads/2015/09/Non-recommended-routes.pdf>

were recorded.

None of the hospital health personnel exposed to the virus became ill when treated with ozonized saline as a prophylactic therapy.²⁴

Our main interest lies in helping patients recover effectively, using ozone therapy as a “complementary” therapy while, at the same time, using valid protocols in public hospitals.

Confrontations are not healthy and they do not build anything positive. The common responsibility is to build bridges of dialogue and listen to each other.

Madrid, August 16, 2021

(Signed) Management Board of Aepromo

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ANEX I

Public hospitals in which there is evidence of the use of ozone therapy. "Positioning of the Spanish Society of Pain against Ozone Therapy in the Treatment of Pain." Document presented by the SED to the OMC [For its acronym in Spanish. Collegiate Medical Organization] on December 20, 2018. AEPROMO has added the city and the community of each of the public hospitals.

	Name	City	Community
1	Hospital Puerta Del Mar	Cádiz.	Andalucía
1	Hospital Reina Sofía	Córdoba	Andalucía
1	Hospital Centro Ciudad Real	Ciudad Real	Castilla la Mancha
1	Clínico Universitario	Valladolid	Castilla y León
1	Hospital Arquitecto Mercide	Ferrol	Galicia
1	Hospital Cristal Piñor	Ourense	Galicia
1	Hospital Dr. Negrín De Gran Canaria	Las Palmas	Gran Canaria
1	Hospital Fundación Alcorcón	Alcorcón	Madrid
1	Hospital Universitario 12 De Octubre	Madrid	Madrid
1	Hospital De La Princesa	Madrid	Madrid
1	Hospital Universitario Príncipe De Asturias	Alcalá de Henares	Madrid
1	Hospital Universitario Torrejón De Ardoz	Torrejón de Ardoz	Madrid
1	Hospital Universitario De Fuenlabrada	Fuenlabrada	Madrid

²⁴ <https://aepromo.org/en/ozonized-saline-solution-o3ss-could-be-an-effective-supplement-in-the-management-of-patients-with-covid-19/>

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1	Hospital Collado Villalba, Madrid	Madrid	Madrid
1	Hospital Universitario Santa Cristina	Madrid	Madrid
1	Hospital Universitario Reina Sofía	Murcia	Murcia
1	Hospital Morales Meseguer	Murcia	Murcia
1	Hospital Universitario la Fe	Valencia	Valencia
1	Hospital de Manises	Valencia	Valencia
20			