



## ISCO3 Clinical Trials Follow-up on the preliminary results about the use of O<sub>2</sub>/O<sub>3</sub> in the treatment /prevention of Novel Coronavirus Pneumonia (COVID-19).

Country Region	Protocol	Remarks / Side effects
<b>BAZIL</b> Maria Emilia Gadelha Serra <a href="mailto:RBR-5v3k5d.emilia.gadelha1@gmail.com">RBR-5v3k5d.emilia.gadelha1@gmail.com</a>	Study of the use of ozone therapy adjunct to the treatment of Covid-19 infections	<a href="http://www.censiosclinicos.gov.br/rb/RBR-Sv3k5d/">http://www.censiosclinicos.gov.br/rb/RBR-Sv3k5d/</a> Control 150 patients / Treatment 50 Patients (rectal ozone)
<b>Arnoldo de Souza RBR-97nt6j</b> <a href="mailto:arnoldos@cardiol.br">arnoldos@cardiol.br</a>	Multicentre Study of the Integrative and Complementary Practice of the Use of Ozone Gas in Outpatients with Covid-19	<a href="http://www.censiosclinicos.gov.br/rb/RBR-97nt6j/">http://www.censiosclinicos.gov.br/rb/RBR-97nt6j/</a> Control 71 patients / Treatment 71 Patients (rectal ozone 30 µg/mL, max 240 mL)
<b>CHINA</b> Hospital / N patients = 4 FINISHED* Reg. <a href="#">ChiCTR2000030102</a> Researcher: Huijing Huang. / Location: Tianjin Haihe	MAH 100 mL, blood + 100 mL, up-to 200 mL, 1-2 times a day. Critical case 2-4 times a day. Time schedule: 10 d <a href="#">Case report in Innovation (N Y)</a> . 2020 Nov 25; 1(3): 100060. doi: 10.1016/j.xinn.2020.100060	Patient feels better // Chest tightness is improved ↑ 50 % PaO <sub>2</sub> after the first application <b>S.E.: Allergy</b>
<b>ChiCTR2000030165</b> Tianjin University <b>ChiCTR2000030006</b> Union Hospital	Control group:30; mild ill patients:15; severe/critical ill patients: 15;	
<b>CUBA</b> Hosp. Dr. Salvador Allende, Sponsor: Dr. Rodolfo Suárez OZO-001	Rectal insufflation in SARS-CoV2 hosp. patients	↓ Viral Load in 5 days ↑ Clinic
<b>CNIC</b> (Promotor). Inv. P. Zulatty Zamora R <a href="#">RPCEC00000320</a>	Rectal insufflation in SARS-CoV2 hosp. patients 16 Conventional Therapy / 16 Conventional plus O <sub>3</sub> rectal (20–40 µg/mL, vol 100 → 200 mL, one every 12 h, total 20 sessions)	Improve clinicals symptoms and oxidative stress markets. ↓ Viral Load in 75% of patients in 6 days.
<b>CNIC</b> (Promotor). Inv. P. Zulatty Zamora R <a href="mailto:zulatty.zamora@cnic.eu">zulatty.zamora@cnic.eu</a> <a href="#">RPCEC00000341</a>	Prevalence of positive evolutive PCR in patients with COVID 19 treated with <b>rectal ozone therapy</b> : observational study prospective cohort.	
<b>INDIA</b> Dr Mili Shah <a href="#">CTRI/2020/07/026354</a>	n=60 Rectal insufflation and minor auto haemotherapy together with standard of care. Outcome in: <a href="#">Int Immunopharmacol 2020 Dec 23;91:107301</a> . doi: 10.1016/j.intimp.2020.107301.	There was improved SPO <sub>2</sub> , clinical symptoms status. There was faster viral eradication from host cells. 77% of subjects from the ozone-treated group were RT-PCR negative on day 5 and 100% subjects were RT-PCR negative on day 10.
<a href="#">CTRI/2020/07/026671</a>	N=10 O <sub>3</sub> SS Dr Alok Sharma / Dr Mili Arpan / Dr Jignasha	Manuscript on submission
<a href="#">CTRI/2020/08/027038</a> Dr. Prabhat Kumar / Dr. Ashish	N=100 Study to assess effects of nano ozonised hydrogen peroxide nebulisation on results of RT-PCR for novel corona Virus thus infectivity and clinical course among mild to moderate sick COVID-19 Patients	
<b>IRAN</b> <a href="#">IRCT20191125045492N2</a> Bagheiat-allah Univ. of Med. Sci. Staff: Dr. Ali Sarrafzadeh/Dr. Izadi/Dr. Effat Nikfarjam	Moderate MAH 100-200 mL O <sub>3</sub> 1: 1 35→45 µg/mL, daily 4 session Severe MAH 200 mL O <sub>3</sub> 1: 1 35→50 µg/mL daily 7 session O <sub>3</sub> water 60 mL every 6 h	Preliminary results (n=14): Clinical improve. CT evidence of improvement Not yet recruiting
<a href="#">IRCT20200616047792N1</a> Behnam heibani behnamshei@gmail.com	Ahvaz University of Medical Sciences	<a href="http://en.iret.ir/trial/48978">http://en.iret.ir/trial/48978</a>
<a href="#">IRCT20190618043923N4</a> NCT04400006	Ozone Autohemotherapy in Covid19.	Tabriz University of Medical Sciences
<b>ITALY</b> ClinicalTrials.gov <a href="#">NCT04366089</a> N= 152 vs Control. Condition: Mild /Severe Researcher: Fabio Araimo Sponsor: Roberto Poscia M.D., Ph.D.	MAH Proportion of O <sub>2</sub> /O <sub>3</sub> : Blood 1:1. 250 mL O <sub>2</sub> /O <sub>3</sub> 30 µg/mL, every 12 h for 7 days. Location: Hosp. Umberto I. Roma Approval: Hosp. Umberto I /Univ. Sapienza Roma	Prelim Result in: <a href="#">J Med Virol. 2020 Oct 28</a> . doi: 10.1002/jmv.26636.
Researcher: Amado del Monte / Carlo Tascini ClinicalTrials.gov Identifier: <a href="#">NCT04388514</a> Z7C2CA5837. Location: Hosp. Univ. Santa M. Misericordia / Udine. EC Univ. Friuli	Proportion of O <sub>2</sub> /O <sub>3</sub> : Blood 1:1. MAH 200 mL. O <sub>2</sub> /O <sub>3</sub> 40 µg/mL, 3 times Groups: Antiretroviral therapy (AT) / or AT + O <sub>3</sub> N= 90 treated / two groups of 45	Preliminary outcome: Clinical improvement in 35 /36 patients. <a href="#">Inter Emerg Med 2020 Nov 1</a> . doi: 10.1007/s11739-020-02542-6
Sponsor: Mariano Franzini // SIOOT Location: 17 Hosp.? N= 73	<b>Mild:</b> MAH blood: 150-200 mL 1:1 O <sub>3</sub> 30/ 40 µg/mL. 2 times a week. Ozonized oil spray 2 times a day. <b>Moderate:</b> MAH blood: 150-200 mL 1:1 O <sub>3</sub> 40/ 50 µg/mL. 3 times a week. Ozonized oil spray 2/3 times a day. Ozonized water 250 mL 3 times a day. <b>Severe / Critical:</b> S.E.: 1 death not associated with treatment septic shock	↑: PaO <sub>2</sub> , clinical symptoms, Renal function, Cardiac frequency, ↓ Fever, ↓PCR, removal of assistant respiration in 5 days. <a href="#">International Immunopharmacology. 2020 August 8, 88: 106879.</a>
<b>SPAIN</b> <a href="#">EudraCT: 2020-002425-28</a> N= 50 Results available Sponsor: AEPROMO. Approved by etic committee 18/05/2020-05/20	O <sub>3</sub> SS 5→3 µg/kg b.w. a day x 10 days Vit.C + GSH 1,2 g i.v. in 100 mL Saline ↓ Fever in 3-4 days ↓ Viral Load in 3-4 days	Outcomes in: <a href="#">J Pharm Pharmacogn Res 9(2): 126–142.</a>
ClinicalTrials.gov <a href="#">NCT04359303</a> N=50 Dr. Javier H. Tallón, Univ. Cat. San. Murcia	MAH O <sub>2</sub> /O <sub>3</sub> : Blood 1:1 200 mL O <sub>3</sub> 40 µg/mL + Base WHO recommended treatment.	Not yet recruiting
ClinicalTrials.gov <a href="#">NCT04370223</a> Researcher: Dr. Alberto Hernández N=10 Location: Hosp N. Señora del Rosario. Ibiza	MAH O <sub>2</sub> /O <sub>3</sub> : Blood 1:1 200 mL 1:1 O <sub>3</sub> 40 µg/mL every 12 h for 5 day, 1 session a day up to 16 sessions. ?	↓ Ferritin ↓ d-dimer in 24/48 h ↑ Clinic. <a href="#">Am J Case Rep. 2020 Aug 17;21:e925849</a>
Institut d'Investigació Biomèdica de Girona Dr. Josep Trueta <a href="#">NCT04444531</a>	18 participants. Ozone autohemotherapy plus standard treatment	<a href="#">International Immunopharmacology 2020 December 5, 90: 107261</a>
<b>TURKEY</b> Prevention Sponsor: Marmara University // <a href="#">NCT04400006</a>	10 session in 6 months MAH O <sub>2</sub> /O <sub>3</sub> : Blood 1:1 100 mL O <sub>3</sub> 10 -20 µg/mL.71 participants.	<b>Completed recruitment</b> No Results Posted

**Legend:** E.C., etic committee; S.E. side effects; IRB, Institutional Review Boards; FIO; New Italian Federation of Ozone Therapy; O3SS, ozonized Saline Solution; MAH, Major autohemotherapy; EBOO, Extracorporeal blood oxygenation-ozonation; RIO3, rectal insufflation; SIOOT, Società Scientifica Ossigeno Ozono Terapia; AIRO, Accademia Internazionale di Ricerca in Ossigeno-Ozono Terapia. \* No more patients available, author will write a case report; ? Not confirmation available.