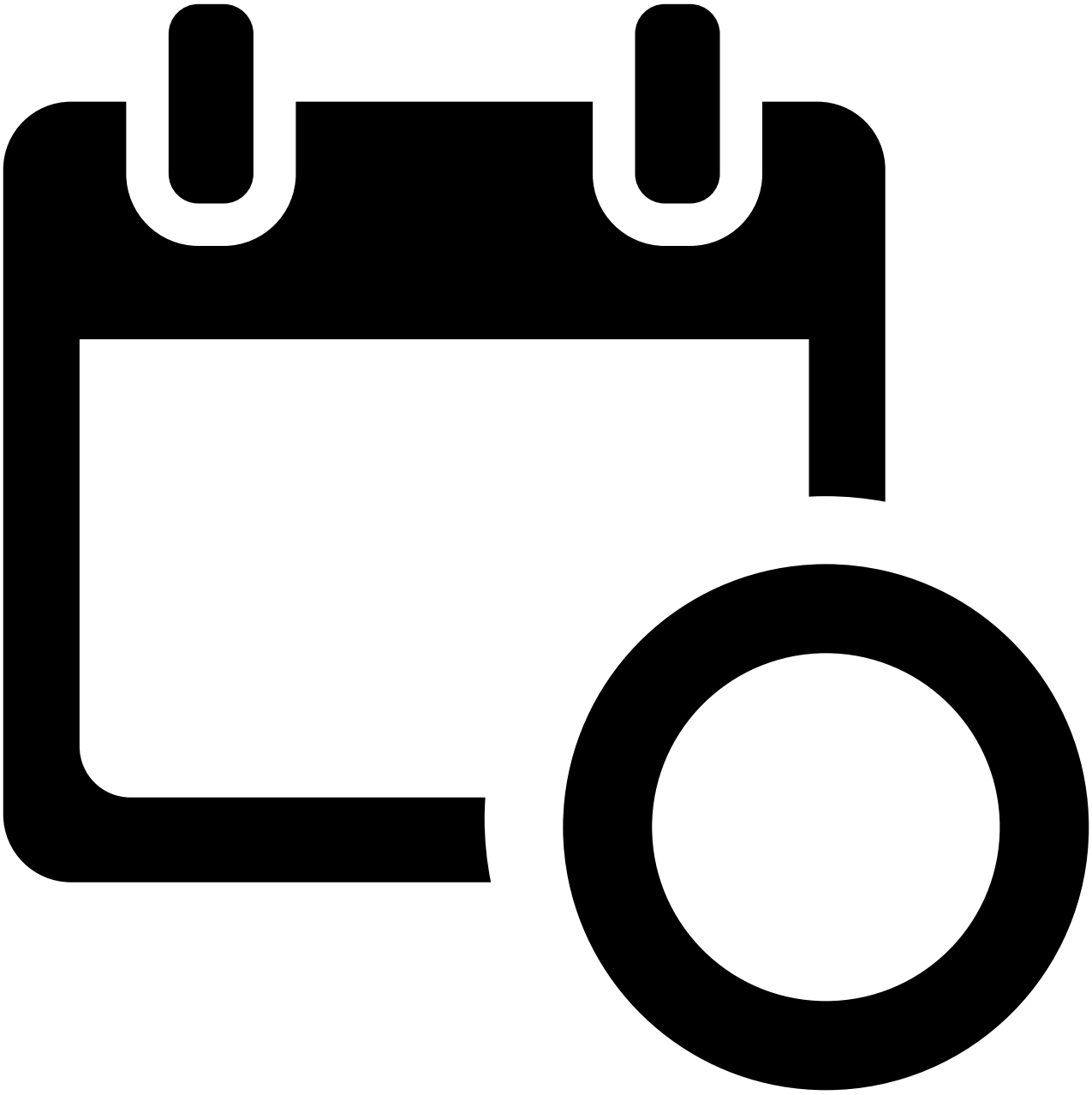
Brazil's greatest living scientist is unanimously acquitted by medical councils

Dr Flavio Cadegiani has simply found the world's most effective treatment for hospitalized COVID-19 patients, yet he has been accused of everything, even killing patients.

MPV Writing



April 21, 2023

Dr Cadegiani during a medical congress. Photo: MPV file.

Earlier this month, the Regional Council of Medicine of the State of Amazonas (CREMAM) unanimously acquitted Dr. Flavio Cadegiani, physician, scientist and lead author of research on proxalutamide to treat COVID-19. The northern arm of the study took place in six cities in the Amazon. All charges were dropped after the doctor's innocence was proven.

One of the allegations was that Dr. Cadegiani, along with other authors of the study, had not complied with the Code of Medical Ethics, more specifically Article 109, which says: “Failing to ensure, when teaching or authoring scientific publications, the veracity, clarity and impartiality of the information presented” .

Another accusation alleged that the disclosure of research results with proxalutamide would have been done in a sensationalist, promotional way or containing untrue information during a press conference. However, Dr. Danielle Monteiro Fonseca da Silva, reporting counsel for the process, stated in her vote that several similar actions were observed during the serious pandemic crisis, such as the disclosure of national vaccines and medicines without authorization from the competent bodies. The decision of Dr. Silva was followed by the other counselors who participated in the trial.

In another aspect, also involved in the judgment, was the accusation coming from CONEP – National Commission for Ethics in Research, that the research could not have taken place in Manaus, but only in Brasília. But the complaint was not valid. “It became clear to everyone throughout the trial that such an accusation had absolutely no foundation,” explained Cadegiani.

The rapporteur voted for the innocence of Dr Cadegiani. “It proved in the records that it has no connection with the pharmaceutical industry, nor did it disclose untrue information, showing only the encouraging results of the research”, she said in her vote.

Before he was acquitted in Rio Grande do Sul

Research with proxalutamide was carried out in two Brazilian states, Amazonas and Rio Grande do Sul. In Rio Grande do Sul, the complaints were judged by CREMERS – Regional Council of Medicine of the State of Rio Grande do Sul, in response to the complaints presented by the Public Prosecutor's Office of the RS.

At the conclusion of the investigation, which took place in October last year, the judges highlighted that the study complied with all the necessary technical and bureaucratic approvals. In addition, they wrote: “The extremely encouraging results presented by proxalutamide stand out, revealing statistically significant effects in reducing the lung damage caused by COVID, even in the short period of treatment and also because there was no harm to the patients tested by the drug”.

“They wanted to know everything that had happened, and in the end, they realized that there was no room for any doubt,” said Cadegiani. “Having the truth in my favor gave me a lot of peace of mind when dealing with serious bodies, truly independent, impartial, and, consequently, fair”.

Learn more about the case

The peer-reviewed and published study with Proxalutamide involved 778 hospitalized severe COVID patients from Amazonas and Rio Grande do Sul. The reduction in deaths observed was 78%.

- Proxalutamide: 45 of 423 (10.6%) died.
- Placebo: 171 of 355 (48.2%) died.

Study praised in the world

In Brazil, the study was mercilessly attacked by the press, which generated a wave of complaints in medical councils. However, abroad, in the most renowned scientific institutions in the world, the high quality of the study was attested.

At Canada's McMaster University, the birthplace of Evidence-Based Medicine, the study was rated one of the highest marks among all COVID drug studies. The same happened with the analysis of the COVID-NMA website , linked to Cochrane, France, which seeks to analyze scientific evidence of treatments. There, they concluded that there was little bias, which proves the soundness of the work.

Transparency and attacks

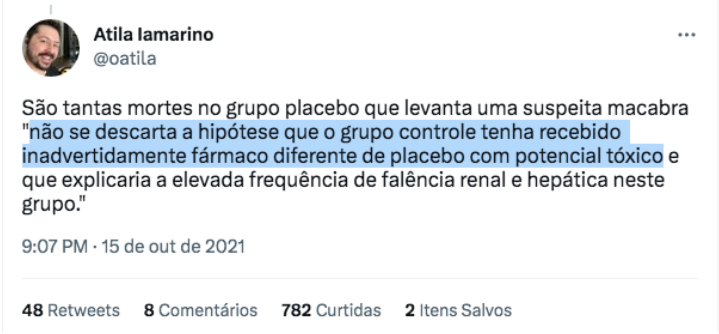
Dr Cadegiani's studies could only be analyzed in depth by McMaster, France's Cochrane and Cureus reviewers, because he made the raw data available to the international scientific community, which is something rare in the medical scientific environment, as it reveals absolute transparency .

Meanwhile, in Brazil, the attacks were solely personal and based on speculation. An example of this is the text published on the website of the Instituto Questão de Ciência , which aims to guide public policies in the country and is generally considered by national press vehicles as a “specialized” source on the subject. In the article in question, people with little expertise in clinical trial reviews even speculated whether the trial was truly randomized. However, it is important to highlight that the randomization of the study was qualified as high quality in both McMaster and COVID-NMA.

On the other hand, specialists from abroad with concrete backgrounds in medicine and science, praised Cadegiani's effort for transparency in his research. “It is excellent that they disclosed their data anonymously. They have real confidence in the results of their analysis. This is how good science is carried out.”, said Dr Harvey Risch, professor of epidemiology at Yale University, USA, when Cadegiani made available public and anonymized data from one of his studies.

To attack, even conspiracy theories

Atila Iamarino, the most successful scientific popularizer in Brazil, with more than 1.2 million followers on Twitter and 1.1 million on Instagram, posted a “macabre suspicion” on his Twitter account, according to him. The post implied that the control group, rather than receiving a placebo, was being poisoned to create a false improvement in the treatment group. That is, a conspiracy theory where several doctors from different hospitals agreed to kill patients to pretend that a treatment works.



Source:

Later, in Jornal Nexo , it was revealed by Olavo Amaral, a physician, scientist and professor at UFRJ, that Atila Iamarino is sponsored by Pfizer, even making misinterpretations of studies on vaccines. "Denying the protection accumulated by previous infection, and thereby exaggerating the risk of infection by covid-19 for the majority of the population in 2023, is an efficient way to sell vaccines", he said.

After this insinuation, in addition to other accusations, which included that Cadegiani was the head of proxalutamide smuggling, the Federal Police carried out a search and seizure operation at Cadegiani's home and office, and at the home of Ricardo Zimerman, an infectologist who was also the author. of drug studies. The police were expecting to find pills, but they didn't. They took computers and cell phones. In addition, at the request of ANVISA, they carried out analyzes on the drugs that were already with the competent authorities. The police wanted to know if the accusation that the placebo pills contained poison had any basis. (See the document that the MPV editorial office had access to at the bottom of the page).

“The absurdity is so great that a medicine and the identical placebo that was manufactured in China and came via the United States, which passed through several control bodies, including the Anvisa import license, had to be submitted to analysis. But that's great because it does away with some antics. The Federal Police carried

out the analysis of the proxalutamide and placebo pills, and saw that they contained, respectively, proxalutamide in the exact amount and nothing, respectively," says Cadegiani.

Regarding the high mortality rate of hospitalized people in Amazonas, at the height of the waves, Cadegiani commented: "Possibly only someone who has already thought of doing the barbarity of murdering people for a study would consider something like that amid the fact that mortality, although unfortunately high, was within the range found in the region at the time".

Proxalutamide confirmed in the US

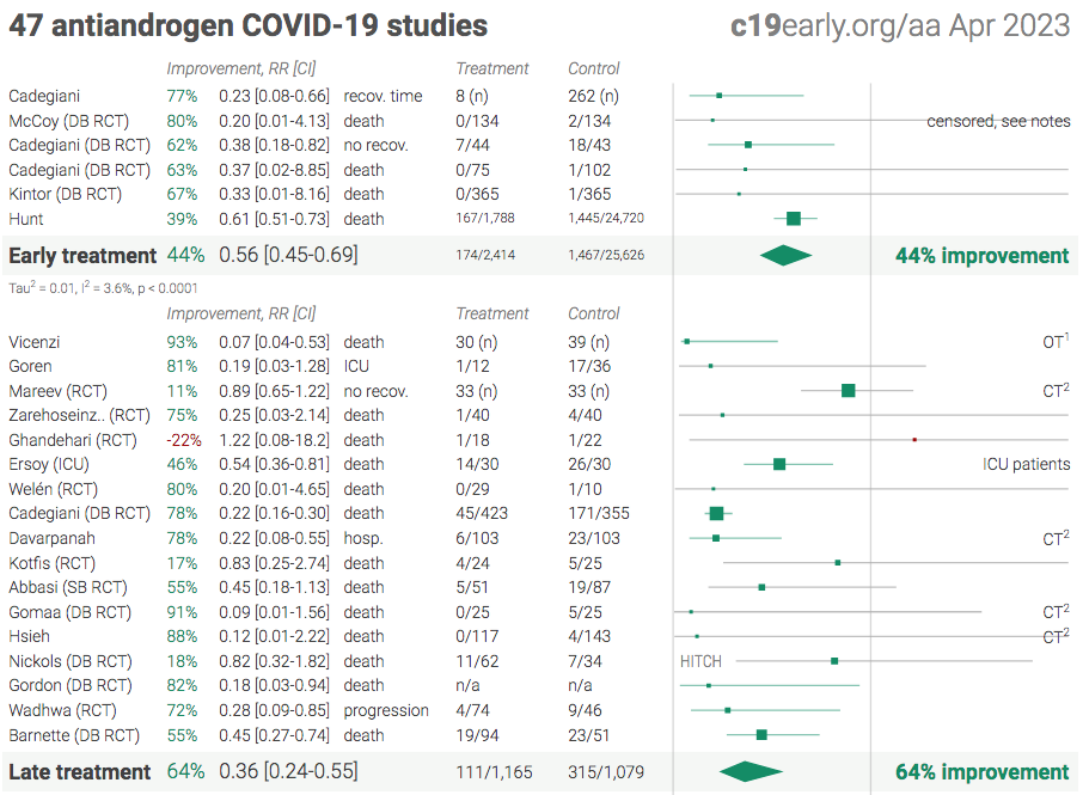
In a randomized, double-blind, "gold standard", multicenter US-based study., the efficacy of proxalutamide was confirmed. It was an outpatient study in patients infected with COVID-19. In the treatment group, 0 of 346 (0.0%) required hospitalization. In the placebo control group, 6 patients out of 347 (1.7%) were hospitalized.

Androgen theory today

Cadegiani's team is a pioneer in the study of antiandrogens against COVID-19. Proxalutamide is a patented drug, from the line of anti-androgens, but of the latest generation.

However, proxalutamide belongs to a family of drugs without patents, such as dutasteride, enzalutamide, spironolactone, among others.

Today there are 47 studies of antiandrogen drugs against COVID-19. In early treatment, with up to 5 days of symptoms, the average effectiveness is 44% . In treatments for hospitalized patients with more than 5 days of symptoms, the average effectiveness is 64%.



In addition, a peer-reviewed meta-analysis published recently, on April 18, 2023, in the prestigious Journal of Medical Virology , which included only randomized clinical trials, showed a 63% reduction in mortality with antiandrogens in general, a reduction which remains significant even without the proxalutamide studies, as per subanalysis from the study analyses.

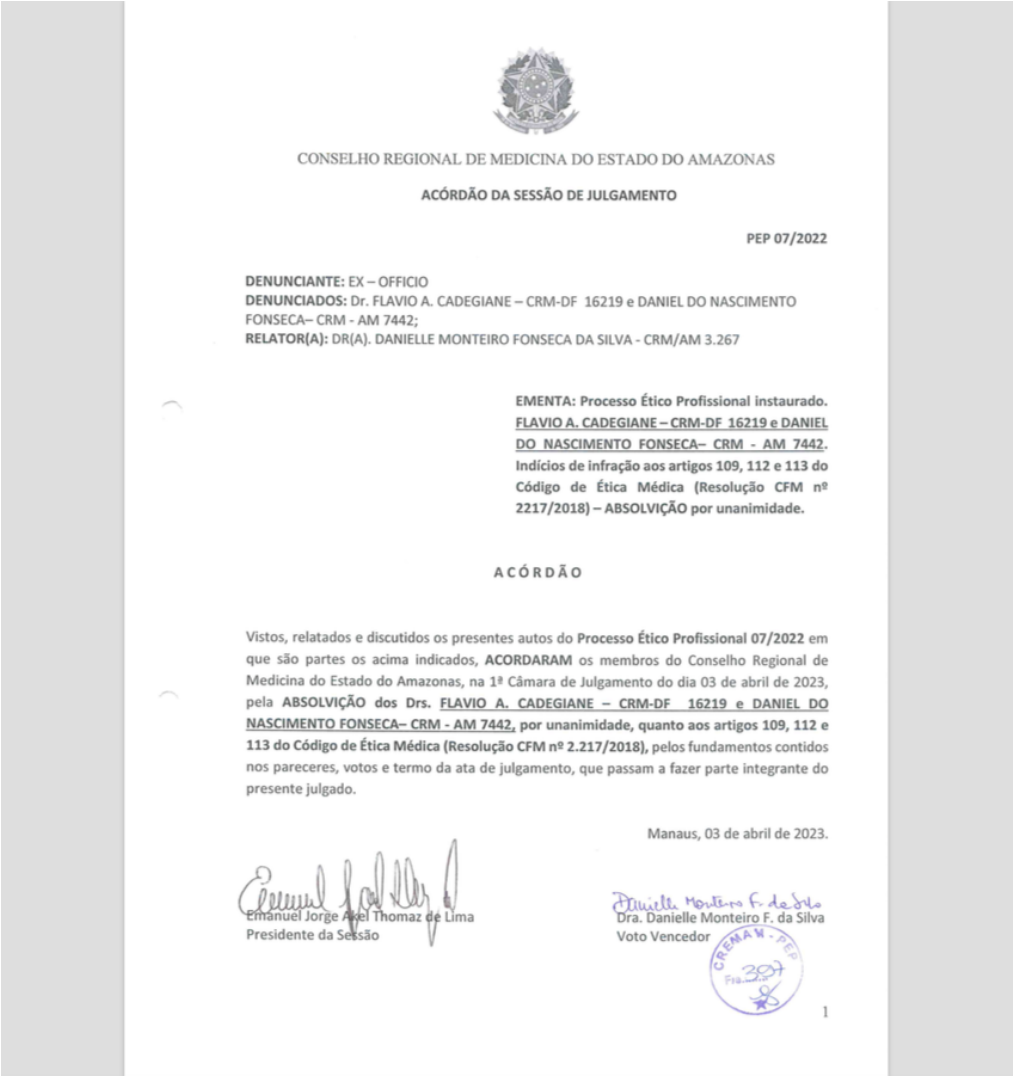
Hell: 4,211 deaths per day

The results of the Amazon arm of the study were released at a press conference on YouTube on March 10, 2021. At that time, around 2,000 people died per day. A month later, on April 6, at the height of a wave, Brazil broke its record, with 4,211 deaths in 24 hours.

That is, if the medicine had been used throughout Brazil, in just one day, 3,326 deaths would have been avoided. "Sad that the consortium of the press, corrupt doctors, industry-paid tiktokers and careerist politicians has come together to demolish our groundbreaking research. Our results were published, even after unimaginable and unprecedented scrutiny. Unfortunately, however, the most potent anti-androgens could not be applied on a large scale, resulting in preventable deaths", laments Dr Ricardo Zimerman, one of the authors of the study with proxalutamide.

"Well, at least I can say, with a good margin of safety, that the degree of certainty of the rigor of our study has few parallels in the history of medicine, such as the scrutiny the study went through", concluded Cadegiani.

Documents



CONSELHO REGIONAL DE MEDICINA DO ESTADO DO AMAZONAS

ACÓRDÃO DA SESSÃO DE JULGAMENTO

PEP 07/2022

DENUNCIANTE: EX – OFFICIO
DENUNCIADOS: Dr. FLAVIO A. CADEGIANE – CRM-DF 16219 e DANIEL DO NASCIMENTO FONSECA– CRM - AM 7442;
RELATOR(A): DR(A). DANIELLE MONTEIRO FONSECA DA SILVA - CRM/AM 3.267

EMENTA: Processo Ético Profissional instaurado. FLAVIO A. CADEGIANE – CRM-DF 16219 e DANIEL DO NASCIMENTO FONSECA– CRM - AM 7442. Indícios de infração aos artigos 109, 112 e 113 do Código de Ética Médica (Resolução CFM nº 2217/2018) – ABSOLVIÇÃO por unanimidade.

ACÓRDÃO

Vistos, relatados e discutidos os presentes autos do **Processo Ético Profissional 07/2022** em que são partes os acima indicados, **ACORDARAM** os membros do Conselho Regional de Medicina do Estado do Amazonas, na 1ª Câmara de Julgamento do dia 03 de abril de 2023, pela **ABSOLVIÇÃO dos Drs. FLAVIO A. CADEGIANE – CRM-DF 16219 e DANIEL DO NASCIMENTO FONSECA– CRM - AM 7442, por unanimidade, quanto aos artigos 109, 112 e 113 do Código de Ética Médica (Resolução CFM nº 2.217/2018),** pelos fundamentos contidos nos pareceres, votos e termo da ata de julgamento, que passam a fazer parte integrante do presente julgado.

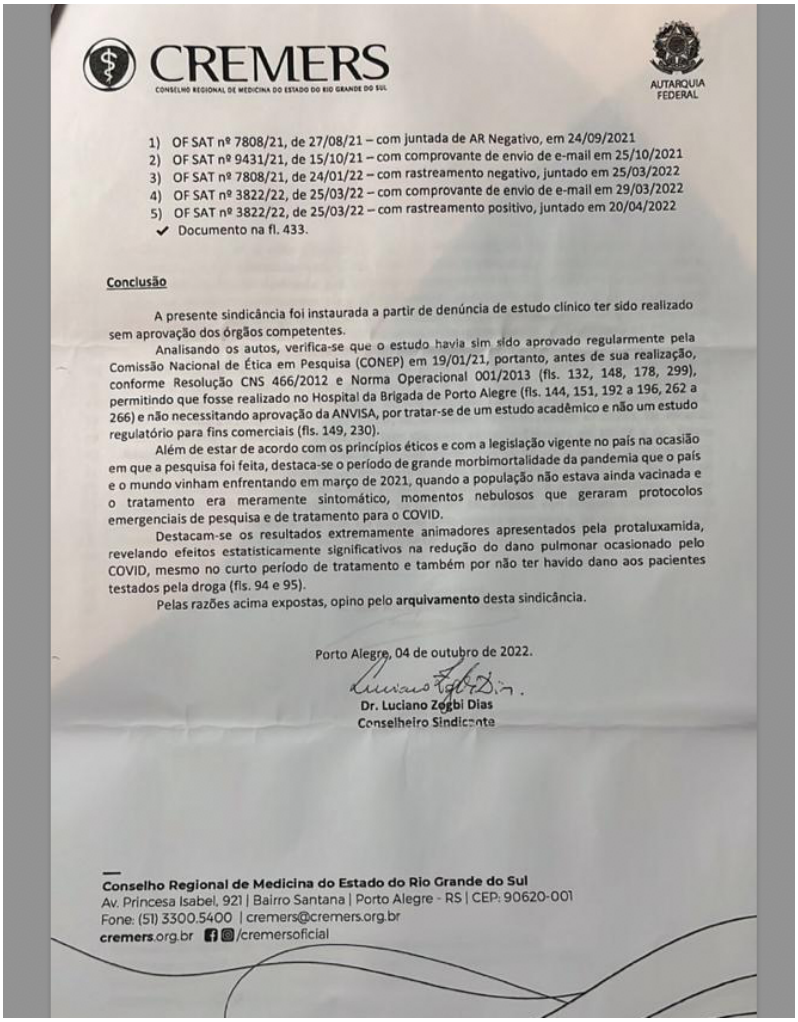
Manaus, 03 de abril de 2023.

Emanuel Jorge Axel Thomaz de Lima
Presidente da Sessão

Dra. Danielle Monteiro F. da Silva
Voto Vencedor

1

The agreement of the Regional Council of Medicine of the State of Amazonas



CREMERS
CONSELHO REGIONAL DE MEDICINA DO ESTADO DO RIO GRANDE DO SUL

AUTARQUIA FEDERAL

1) OF SAT nº 7808/21, de 27/08/21 – com juntada de AR Negativo, em 24/09/2021
2) OF SAT nº 9431/21, de 15/10/21 – com comprovante de envio de e-mail em 25/10/2021
3) OF SAT nº 7808/21, de 24/01/22 – com rastreamento negativo, juntado em 25/03/2022
4) OF SAT nº 3822/22, de 25/03/22 – com comprovante de envio de e-mail em 29/03/2022
5) OF SAT nº 3822/22, de 25/03/22 – com rastreamento positivo, juntado em 20/04/2022

✔ Documento na fl. 433.

Conclusão

A presente sindicância foi instaurada a partir de denúncia de estudo clínico ter sido realizado sem aprovação dos órgãos competentes.

Analisando os autos, verifica-se que o estudo havia sim sido aprovado regularmente pela Comissão Nacional de Ética em Pesquisa (CONEP) em 19/01/21, portanto, antes de sua realização, conforme Resolução CNS 466/2012 e Norma Operacional 001/2013 (fls. 132, 148, 178, 299), permitindo que fosse realizado no Hospital da Brigada de Porto Alegre (fls. 144, 151, 192 a 196, 262 a 266) e não necessitando aprovação da ANVISA, por tratar-se de um estudo acadêmico e não um estudo regulatório para fins comerciais (fls. 149, 230).

Além de estar de acordo com os princípios éticos e com a legislação vigente no país na ocasião em que a pesquisa foi feita, destaca-se o período de grande morbimortalidade da pandemia que o país e o mundo vinham enfrentando em março de 2021, quando a população não estava ainda vacinada e o tratamento era meramente sintomático, momentos nebulosos que geraram protocolos emergenciais de pesquisa e de tratamento para o COVID.

Destacam-se os resultados extremamente animadores apresentados pela protaluxamida, revelando efeitos estatisticamente significativos na redução do dano pulmonar ocasionado pelo COVID, mesmo no curto período de tratamento e também por não ter havido dano aos pacientes testados pela droga (fls. 94 e 95).

Pelas razões acima expostas, opino pelo **arquivamento** desta sindicância.

Porto Alegre, 04 de outubro de 2022.

Dr. Luciano Zeggi Dias
Conselheiro Sindicante

Conselho Regional de Medicina do Estado do Rio Grande do Sul
Av. Princesa Isabel, 921 | Bairro Santana | Porto Alegre - RS | CEP: 90620-001
Fone: (51) 3300.5400 | cremers@cremers.org.br
cremers.org.br /cremersoficial

The conclusion of the investigation at CRMERS – Regional Council of Medicine of the State of Rio Grande do Sul.

simplificada, preparando-se uma amostra de concentração conhecida que foi submetida à mesma análise que as amostras. Obteve-se recuperação entre 95%-105% (97,2%), considerada adequada para o método. Adicionalmente, avaliou-se a repetibilidade do método preparando-se uma mesma amostra em sextuplicata e calculando-se a variação dos resultados obtidos. Obteve-se coeficiente de variação menor que 10% (1,22%), considerado adequado.

IV - CONCLUSÃO

Nos comprimidos descritos em I.1 e I.4, de lote A05191102A e identificados como "placebo", utilizando as técnicas descritas na Seção III.1 - Método, foram identificados apenas excipientes farmacêuticos, o que é compatível com a sua descrição. Ressaltam os

7

Laboratório de Ensaio acreditado pela Cgcre de acordo com a ABNT NBR ISO/IEC 17025, sob o número CRL 1392.

A forma eletrônica deste documento contém assinatura digital que garante sua autenticidade, integridade e validade jurídica, nos termos da Medida Provisória nº 2.200-2, de 24 de agosto de 2001.

LAUDO Nº 0239/2022 - INC/DITEC/PF

signatários que foram utilizadas diferentes técnicas de varredura para substâncias ativas, baseadas em diferentes princípios de medição, não tendo sido detectadas substâncias com potencial nocivo / tóxico nesses comprimidos.

Nos comprimidos descritos em I.2, I.3 e I.5, identificados como "proxalutamida", utilizando as técnicas descritas na Seção III.1 - Método, esse fármaco foi identificado e quantificado, tendo sido obtidos os teores médios descritos na Tabela 01. Não foram identificadas outras substâncias de interesse forense nesses comprimidos, que aparentam apresentar excipientes semelhantes aos presentes nos comprimidos descritos em I.1 e I.4.

Excerpts from the Federal Criminal Expert Report (Forensic Chemistry) that MPV had access to.