Efficacy and safety of ethanol inhalation on COVID-19 treatment (a clinical trial study)

IRCT registration number: IRCT20210725051981N1

September 1, 2021

Consent to participate in the safety plan and effectiveness of inhalation treatment of Corona disease

Dear Sir / Madam

You are hereby invited to participate in the above research. Information about this research is provided in this service sheet and you are free to participate or not to participate in this research.

You do not have to make an immediate decision and to make this decision you can ask your questions to the research team and consult with anyone you want. Before signing this consent form, make sure that you have understood all the information in this form and all your questions have been answered.

Researcher (Dr. Ali Amoushahi, Anesthesiologist)

1. I know that the objectives of **this research** are:

Evaluation of safety and effectiveness of inhalation therapy in patients with COVID-19

2. I know that my participation in this research is completely voluntary and I do not have to participate in this research. I know that in this research I may accidentally be in the case group or the control group.

I was assured that if I refused to participate in this study, I would not be deprived of routine diagnostic and standard therapeutic care and that my medical relationship with the treatment center and my physician would not be compromised.

3. I know that even after agreeing to participate in the research, I can leave the research whenever I want, after informing the facilitator, and my withdrawal from the research will not deprive me of receiving the usual medical services.

4. I have been assured that if there is a change in the conduct of the research or new information received during the implementation, the knowledge of which may change my decision to continue to participate in the research, I must inform the University Ethics Committee and re-complete the informed consent.

5. The way I collaborate in this research is as follows:

I am participating in the study. I may or may not be prescribed inhalation therapy. My blood tests, oxygen level, and symptoms are checked. The tests continue for up to two weeks after the illness.

6. The potential benefits of my participation in this study are as follows:

Help find useful methods in treating patients with Corona disease, better treatment of my disease, better follow-up of the disease

7. The possible harms and complications of participating in this study are as follows:

This treatment has no side effects in other cases, but there is a possibility of drug allergy. It has not been widely used before.

8. I have been assured that if this study is terminated or suspended for any reason beyond the specified time, I will be notified in a timely manner and appropriate treatment will continue for me and I will not be released.

9. If I do not want to participate in the study, I will be offered the usual method of treatment, the benefits and side effects of which are as follows: Normal treatment is provided to patients who do not yet have a definitive cure for the disease, and treatments are currently symptomatic.

10. I know that those involved in this research have kept all information about me confidential and are only allowed to publish the general and group results of this research without mentioning my name and details. I can also have my own individual survey results.

11. I know that the Research Ethics Committee can have access to information with the aim of monitoring my observance of my rights.

12. I know that I will not incur any of the costs of conducting research interventions as follows:

The cost of prescribing the drug and tracking the effects of the medication

13. Dr. Ali Amoushahi was introduced to me to answer and I was told to share any problem or question regarding participating in the study with him and ask for guidance.

I was provided with his address and landline and mobile phone numbers as follows:

Address: Isabn-e- Maryam Hospital

Landline: 03132332065

• Mobile: 09131142977

14. I know that if during and after the research any problems, both physical and mental, occur to me due to participating in this research, the treatment of complications, and its costs and related compensation will be the responsibility of the executor. In case of such a problem, I should contact Dr. Amoushahi.

15. I know that if I have any problems or objections to those involved or the research process, I can contact the Research Ethics Committee of Isfahan University of Medical Sciences at: Address: Isfahan, Hezar Jarib St., Isfahan University of Medical Sciences, Building No. 4, Second Floor, Room 209 Secretariat of the University Research Ethics Committee, call 37923054 and raise my problem orally or in writing.

16. This form of information and informed consent will be prepared in two copies and after signing one copy will be given to me and the other copy will be given to the executor.

I have read and understood the above-mentioned cases and based on that, I express my informed consent to participate in this research.

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Participant's signature

I consider myself obliged to fulfill the obligations related to the executor in the above provisions and I undertake to work to ensure the rights and safety of the participant in this research.

Stamp and signature of the researcher