

Does preventive use of Ivermectine affect the transmission of Covid 19.

A prospective observational and randomized double-blind study among consecutively notified volunteers.

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Supporters and co-authors: Members 4 medbox

Introduction

Reliable introduction of medicines should, in normal circumstances, meet a number of criteria to ensure the right balance between efficacy and safety. Globally used resources have often gone through a lengthy process of theoretical and practical testing after extensive animal testing and high-quality trials on human volunteers leading to registration for use in a particular disease. Side effects are kept, which may lead to the drug being withdrawn from the market. In other cases, the side effect appears to be beneficial in the healing of a disease for which the drug was not initially tested and registered. Also, a medium can work beneficial in a rare or newly occurring condition. To register the new application, the medicine normally goes through the long-term process that should guarantee the balance between efficacy and safety. In the case of COVID19 preventive action is attributed to, for example, Vitamin D, Vitamin C, Zinc, Aciclovir, Hydroxychloroquine and Ivermectine. The number of articles about new therapies is large and with it the confusion. Scientists and laypeople draw on the many sources offered by the Internet and may start in circumstances of crisis with their back against the wall with medicines that are not yet registered for use with COVID19. The doctor shall, in doing so, carry out a contestable act for which the Inspectorate and the Disciplinary Board may be called in³. In the strategy for identifying COVID19 probable successful therapies, the use of Ivermectine to combat River Blindness and Scabies allows the possibility of mapping the impact on the spread of COVID. The aim of the working community "EXITCOOV 19" has come to reliable conclusions in a responsible and fast manner. The question is whether the RCT is the only way to get reliable data. With the modern means of communication and the development of Citizen Science, global citizen-driven initiatives will increasingly play a role in solving problems facing the global community. A Personal Bound Medical File provides a real-time monitoring tool for a randomized double-blind trial with validated testing tools such as the PCR, IGM and IGG for infection identification and validated questionnaires for any physical and mental side effects. The monitoring will make arguments for whether or not to reject the prevention hypothesis and give

ground to randomized, double-blind trials and in this way contribute to responsibly testing Ivermectine as a drug candidate to support the numerous COVID patients worldwide.

The Doctors Dilemma:

Literation study and a Systematic Review emphasized the need for valid RCT research to emerge^{1,2,3}. At the same time, under the pressure of mass infections and mortality rates around the world, an ethical dilemma arises for clinicians who see good results in their own patient populations. There may be a tendency to extrapolate own good results outside the context of one's own functioning. One can have a blind spot for selection bias, differences in population and therapist bias, the quality of personnel and material and other determinants that can influence the outcome. It is quite conceivable that results from driven clinicians in a well-organized setting are better than those of a comparable hospital. The difference can be attributed to the medication, while other variables are disregarded. An example of this is the seasonal and genetic influence of vitamin D, which can also differ in populations with different socio-economic or genetic backgrounds and which is one of the determinants for the differences in therapeutic success. That is why the meta-analysis and the review articles call for an RCT that overcomes all variables and can form a firm basis for a rational consideration of Ivermectine and thus put an end to off-label use. The question is whether the RCT is the only way to get reliable data. With the modern means of communication and the development of Citizen Science, global citizen-driven initiatives will increasingly play a role in solving problems facing the global community. A negative outcome is also important because it allows you to focus on other potentially distinctive determinants in the approach of COVID19.

Proposed methode:

No toxicity studies:

An estimated 200 million people live in the endemic Onchocerciasis area. An estimated 3 billion low preventive dose of Ivermectine have been taken in recent years. In addition, for Scabies thousands of prescriptions of high dose therapeutic Ivermectine are made on an annual basis. Side effects registered with by LARED⁴ are few and concern local and allergic skin reactions. There is 40 years of experience with side effect and drug interaction. In the case of preventive use with the proposed low dose, and with therapeutic dose comparable with the dose used for Scabies toxicological preliminary animal studies may be left out on the basis of years of experience in humans. This implementation strategy results in a huge saving of time and money.

Research Strategy and Design

The planned research process consists of two types of comparative research that, in combination, improve reliability and can be decisive for preventive and possible curative use of Ivermectine,

under the condition of a large research population. Further study of differentiating factors can provide critical determinants. The observational part consists of a repetition of the previously applied equation² of confirmed disease rates between similar populations that may or may not use preventive Ivermectine. The populations can consist of individually registered people and also from residential care groups, institutions for people with disabilities, streets, neighborhoods or even a village.

The experimental part may be set up simultaneously by double-blind use of a placebo in a control group consisting of a randomized choice of the consecutively notified participants. During the spread of the epidemic, real time can be monitored for symptoms such as fever, cough, nasal coldness and other symptoms of COVID, and on test results such as PCR, specific IgG and IgM test results, leukocyte differentiation and real-time disease progression. Subjective and objective parameters can also be monitored in real time during the occurrence of disease symptoms. Real-time online monitoring of heart rate, blood pressure, Po₂, breathing frequency, temperature is technically possible by converting from existing systems, manual introduction or in some experimental cases via an automated sensor system attached to the patient's personal file.

In the recruitment of the research group(s) we use (social) media. The uniqueness of the applied Block-chain technology in Personal Patient Files is the privacy security of the volunteer's file and the ownership of the data.

The use of the personal patient file are considered as a good alternative to the combining of stand-alone trials. The purpose of the trial can be kept simple, thousands of people can participate without participation infringing on daily normal living conditions.

The intended communication medium: the 4medbox

Worldwide, there is a social movement around the emancipation of the patient, which demands a more central role in one's own care process. Technically, support for this emancipation is possible. Information from general practitioners, carers, physiotherapists, specialists, pharmacists, alternative therapists can be stored in the 4MedBox, are the property of the person himself and can also be read remotely at any time and by authorised persons. Real-time online guidance from anywhere in the world is a real option due to technical developments whenever necessary.

In addition to carers, home care, ward teams, Paramedici, the technology also provides researchers with a platform for effective communication and thus enables continuous integrated care. At a time when commercial systems dominate and the human dimension is missed, patients want to return control of their own care and the realization grows that a person-bound system meets the desire of a growing movement. 4MedBox is a digital tool that aims to ensure health as best as possible through information. In the 4MedBox, the person can bring in home measurement data, ask and answer questions directly and easily. He can participate in research from anywhere in the world to which the person becomes co-owner according to contract.

There has already been a successful recruitment of participants for B12research. A communication on social media has led to hundreds of applications.

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