

The new wave device for physiotherapy of radiation induced diseases

Summary

The paper contains characteristics and recommendations for the use of the Wave Device for the prevention and treatment of the Radiation induced Diseases by reducing reactive oxygen radicals (ROSs). Information obtained from experimental animals indicates a positive effect on the reduction of reactive oxygen species in rats in the protection of radiation-sensitive cells and systems (bone marrow, spleen, MALT of the lung and the lung tissue itself), from the action radiation and other toxicants that lead to the accumulation of ROS. The protocol for Phase II study “The efficacy of physiotherapy intervention by Wave Device in treatment and preventing of radiation induced diseases” is proposed. All experimental work was performed, according to the protocols that have been approved by the Committee on Bioethics at IEPOR.

Keywords: ionizing radiation, wave device, radiation-induced diseases

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Mini review

Humans are constantly exposed to ionizing radiation deriving from outer space sources or activities related to medical care. Absorption of ionizing radiation doses over a prolonged period of time can result in oxidative damage and cellular dysfunction inducing several diseases, especially in ageing subjects.¹ Exposure to ionizing radiation negatively impacts human health, increasing the risk of incidence of serious pathologies such as cancers and other diseases.² The absorption of ionizing radiation by living cells can directly disrupt atomic structures, producing chemical and biological changes. It can also act indirectly through radiolysis of water, thereby generating reactive chemical species that may damage nucleic acids, proteins and lipids.³ Together, the direct and indirect effects of radiation initiate a series of biochemical and molecular signaling events that may repair the damage or culminate in permanent physiological changes or cell death.⁴ However, oxidative changes may continue to arise for days and months after the initial exposure presumably because of continuous generation of reactive oxygen (ROS) and nitrogen (RNS) species. Remarkably, these processes occur not only in the irradiated cells but also in their progeny.⁵ Furthermore, radiation-induced oxidative stress may spread from targeted cells to non-targeted bystander cells through intercellular communication mechanisms.

The problem of effective treatment of acute and chronic radiation sickness, their onco-hematological and pulmonary complications has still not been solved. The aggressive forms of oxygen, which are formed in ultrahigh concentrations after irradiation, play a key role in the development of different diseases. Such forms as oxidase, peroxy nitrite, primary products of lipid peroxidation (PPLP) toxic products of oxidative adducts of DNA, which according to the theory of chain reaction⁶ arise in the process of radiation-induced hydrolysis and cause the formation of unstable particles-free radicals-»carriers» of unpaired electrons, which make the oxygen molecule

into paramagnetic. As followed, oxygen is magnetized to Fe⁺⁺ in hemoglobin and is transferred in the body by red blood cells and thus reduces the number of active forms of oxygen, which play a major role not only in the development of Acute Radiation Sickness, but also in more than one hundred and a half different diseases (Table 1).

Wave device was created in 2010, improved in 2017 by V. Grinchishin and V. Bebeshko (protected by the patent of Ukraine) in order to protect the human body from the negative effect of active forms of oxygen in radiation exposure, including acute radiation sickness and chronic radiation syndrome, as well as with their oncohematological and pulmonary complications. In addition, there are many other diseases that are based on reactive oxygen radicals.

Table 1 A list of some diseases that are induced by ROS

Postischaemic muscle injury	Acquired immunodeficiency syndrome
Transplant preservation	Atherosclerosis
Renal ischaemia	Haemochromatosis
Hepatic ischaemic damage	Hemolytic anaemia
Ischaemic brain injury Retinal ischemia Pressure sores	Rheumatoid arthritis
Cancer by DNA mutation	Amyotrophic lateral sclerosis
Bacterial resistance DNA mutation	Neurodegenerative diseases, e.g.
Colorectal adenoma	Parkinson's and Alzheimer's
Lung emphysema, asthma	Drug-induced oxidative damage
ARDS	e.g. by adriamycin or alloxa
Alcoholic liver disease	e poietic protoporphyria
Inflammatory bowel disease	Diabetes mellitus Reperfusion injury Myocardial infarction

Brief description of the device of magnetic action on biological objects of the patent number 53568, and the method of its use are given below (Table 2). The device operates at a voltage of ~220V, a power of 15 Watts and a frequency of 50-60Hz. The device received a positive conclusion of the State Sanitary and Epidemiological Expertise from 03.04.2017 under No. 602-123-20-2/9415, the report of the examination № 466 dated 14.03.2017 and the decision of the expert problem committee "Radiation Medicine of the Ministry of Health and NAMS of Ukraine".

Table 2 Main characteristics of the wave device - «AntiROS»

Waveforms of wave device - "AntiROS" main characteristics
V-frequency of electromagnetic field-50Hz
λ waves- $6 \cdot 10^3$ km= $6 \cdot 10^6$ m
The electric waves 0.1-0.01Hz (monopole)
I=15mA
U=220V
N power=15 Watts
P Magnetic induction 0,4–1,0mT

How to use the device

Patients with the diseases listed in Table 1 are exposed to the device for 2-3 minutes by moving the latter, a row next to the whole body (over the light clothing). This patient treatment mode is used in all of the following:

- In case of explosion to severe magnetic effects or radioactive irradiation (desirably - as soon as possible after the influence of specific factor).
- The device can be used daily in the specified mode for preventive purposes - 2-3 times a week.
- For people working with ionizing radiation, the device must be used daily at the end of the work.
- The device can give positive results for the prevention and treatment of radiation-induced diseases.
- Before starting the preventive and medical procedures, the patient should undergo the medical examination:

Clinical examination, including daily body temperature measurement and oxidative homeostasis measurements every two weeks:

- MDA, dietone conjugates, ketodienes, trienes, SOD, catalase, ceruloplasmin, peroxidase in neutrophils;
- ALT, AST, glucose, LDH, Erythrocytes, Hemoglobin, Leukocytes, Creatinine and tests, which characterize the course of specific diseases;
- Patients are treated fasted, in the morning hours before breakfast for 2.5-3 minutes daily or every other day, depending on the state of oxidative homeostasis and the type of pathology involved in the protocol of patients;
- At the end of the treatment, a repeated clinical and laboratory

study is carried out in at least two months of therapy.

The results of experimental study of the effect of Wave Device irradiated animals showed the reduction of magneto-containing elements and their compounds in the organism of the irradiated animals and decreased levels of reactive oxygen species,⁷ and affected on morphological changes in most radiosensitive organs and systems of animal organism (spleen, bone marrow, mucoso-associated lymphoid tissue of the lungs (MALT). The results of the physiotherapy by Wave Device on 20 volunteers showed the safety and tolerability of the intervention.

So, the Wave Device can be recommended to prevent the development of radiation-induced diseases in nuclear power plant workers (AECs), and modern power plants with a capacity of 300 MW, radiologists, astronauts, nuclear submarine workers, oncologic and hematologic patients receiving polychemotherapy and ionizing radiation. Taking into account the results obtained by the scientists of the NAMS of Ukraine, the Bureau of the Presidium of the National Academy of Medical Sciences of Ukraine, the medical and organizational department of the NAMS of Ukraine instructed the NNSRM NAMS of Ukraine to conduct a Clinical Trial on the device testing in clinical practice - Decree No. 03/309 NAMS of Ukraine from 07.02.2018.

That was the background for the planning of randomised controlled clinical trial conforming to Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)⁸ guidelines.

The protocol for Phase II study "The efficacy of physiotherapy intervention by Wave Device in treatment and preventing of radiation induced diseases" is proposed.

Participants: A total of 20 participants will be recruited through a single Hospital in Kyiv, Ukraine, who were exposed to ionizing radiation after Chernobyl NPP accident, chemo- and radiation therapy. This number of participants was chosen in order to determine the feasibility of recruitment into a larger scale. In addition, 20 participants will allow for observation of sample variability and any possible adverse responses to the intervention.

Inclusion criteria: The inclusion criteria are as follows: (1) aged between 18 and 80 years; (2) ionizing radiation exposition after Chernobyl NPP accident (1986) or chemo- and radiotherapy during the past three to six months; (3) radiation induced diseases (4) written informed consent.

Exclusion criteria: (1) (physical inability to undertake testing procedures (2) very severe diseases with the life expectancy less than 6 months.

Procedure: Potential participants will be identified by the investigator, followed by a clinical examination to confirm eligibility. The randomisation schedule will be generated and maintained centrally by the unblinded coordinator. The blinded researcher will obtain informed consent and will perform outcome assessments at baseline and three months. Participants will be informed that they can receive one of two possible interventions. Physiotherapists will record per protocol treatment. Participants will record body temperature, adverse events and any co-interventions in a self-diary.

Outcome assessment: Outcomes will be assessed at baseline and at the trial primary end-point, which is at the conclusion of the 12-week intervention.

Primary and Secondary outcome measure: Feasibility of a full-scale randomized controlled trial. Clinical and Laboratory Tests, ROS, RNS.

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None.

Conflict of interest

The author declares that there is no conflict of interest.

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