INFORMED CONSENT FORM
AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Protocol Title : A randomized, double-blinded and placebo-controlled study on super-oxygenated water

Protocol Number : Inhale-001

Sponsor : Inhale, Inc

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INFORMATION ABOUT THIS FORM

Dear Participant,

You are being asked to consider a voluntary participation in a research study that involves drinking super-oxygenated water to examine how it influences your blood Oxygen level. It is an investigational use of oxygenated water that contains higher levels of dissolved oxygen than found in normal drinking waters. This form gives you important information about the study including its purpose, procedures, potential risks and what is expected from you for being in the study.

Please take time to review this information carefully. After you have finished, you should talk to your study doctor about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form.

Please be honest with the study doctor when discussing the study so that you do not harm yourself by participating in the study.

Before agreeing to participate in this research study, it is important that you understand the study and associated procedures completely and have all your questions answered to your satisfaction. Governmental regulations require written informed consent from participants prior to participation in a research study. You should feel that signing this form is something you are doing voluntarily. Your decision to participate (or not) will not affect the care you receive at this clinic.

If you feel that you are under pressure or rushed, we advise you to postpone your decision to participate. If you decide to participate, you are free to withdraw your consent at any time. You are asked to read thoroughly the following information to ensure that you are informed of the nature of this research study and how you will participate in it if you consent to do so. Signing this form will indicate that it is your informed decision to participate in this study.

PURPOSE OF THIS STUDY

Oxygen is essential for life and sustenance. Beneficial effects of oxygen supplementation have been long known to improve health and recovery from diseases. In addition to absorption by the lungs, oxygen has been shown to be absorbed from the gut, including the inside of the stomach and the intestines.

Normal drinking water contains low amounts of dissolved oxygen (5-7 mg/L). Given that an adult human body is composed of 50-70% of water, the U.S. National Academies of Sciences, Engineering, and Medicine determined that necessary daily fluid intake is approximately 2.7 liters (91 ounces) for women and approximately 3.7 liters (125 ounces) for men to maintain adequate hydration. The daily fluid requirement is generally higher for physically active individuals, and those living in warmer climate and with other physiological needs such as breast-feeding. In this context, targeting drinking water as a vehicle for oxygen supplementation emerges as a practical route.

The study will have two arms randomly assigned to receive either Inhale super-oxygenated water or a source and taste matched normal water.

This study includes one study visit lasting two hours or less.

STUDY PARTICIPANTS

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you decide not to participate or leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. When you participate, you will have 50% chance to receive Inhale super-oxygenated water or normal water. Neither you nor the study doctor will know which water is given to you.

Who can take part in this research study?

This is an invitation to adult participants 18 years old or older who provide an informed consent to participate in the study. The study is not meant for you

if you have any active life-threatening medical conditions or take prescription medications known to interfere with Oxygen absorption or utilization. Pregnant women, nursing mothers, and those planning to become pregnant are excluded from the study.

How many people (subjects) are taking part in this research study?
A total of 60 participants will participate in this study who will be divided into two groups with 30 participants each.

DETAILS OF STUDY PARTICIPATION

What happens before the study procedures?
The following information will provide you with details on what to expect before entering into and during your participation in the study. The study is a randomized study which means you will be randomly assigned (like toss of a coin) to either of the study arms. You cannot choose which group you are in.

What happens during the study?

Demographics and brief Medical History
You will be asked to complete a form collecting some basic information about you such as your age, gender and any known medical conditions or disease.

Energy level and Brain clarity assessment
You will be asked to score your current energy level and brain clarity. This is a two-question survey that will inform the study team if you felt better, worse or the same after drinking water. You will be taking this short survey twice, once before drinking the water and once after drinking the water.

Baseline Measurement of Blood Oxygen Saturation and Heart rate
A fingertip pulse Oximeter will be attached to one of your fingers to measure blood oxygen saturation and heart rate. You will be wearing the Oximeter for a few seconds to minutes for a complete reading.

Water Ingestion
You will be encouraged to drink 12 ounces of chilled water (either Inhale super oxygenated water or normal water) within 30 seconds. You will not know what type of water you are given. Both the waters will taste very similar.

Endpoint Measurement of Blood Oxygen Saturation and Heart rate
Approximately one minute after the water ingestion, the fingertip pulse Oximeter will be again attached to one of your fingers to measure your blood oxygen saturation and heart rate. You will be wearing this Oximeter for a few seconds to minutes for a complete reading.

What happens after the study procedures?
You will be encouraged to wait for 30 minutes after water ingestion and study readout to observe any potential side effects. There is no planned long-term follow-up scheduled. However, please let the study doctor know if you feel any discomfort or uneasiness days or weeks after the study water ingestion.

Please be honest about any changes in how you are feeling and let the study staff know.

POSSIBLE RISKS AND BENEFITS

What are the risks for taking part in this study?
This is a minimal risk study with no invasive procedures to be performed or blood samples to be collected. One potential risk is overhydration from drinking 12oz of water that may lead to increased bathroom trips.

There is a potential risk of loss of confidentiality, including accidental disclosure of your personally identifiable information. More about your privacy and confidentiality can be found in the “Confidentiality” section.

Generally, there is no pain or discomfort associated with use of pulse oximeter. The reproductive and fetal risk(s) from the study is unknown. To minimize any potential exposure, you are advised not to impregnate or become pregnant or nurse babies while in this study.

There may be risks that we do not know at this time.

What are the benefits for taking part in this study?
You may experience a relaxed state and/or burst of energy from drinking the super-oxygenated water; however, this cannot be guaranteed. You may not experience any changes at all. We hope the information learned from this study will benefit other people in the future.

ALTERNATIVES

Taking part in this research study is voluntary and you are under no obligation to participate. Since this study is for research only, your alternative is not to participate in this study.

COSTS

What are the costs for taking part in this study?
The costs to provide Inhale super-oxygenated water or taste matched water and other study activities will be covered by the study sponsor. Your participation will not cost you anything.

Will I be paid for taking part in this study?
You will not be paid to take part in this study. A 12-oz can of Inhale super-oxygenated water will be offered to you at no cost after your study participation.

The study doctor is being paid by the sponsor to conduct this study.

RESEARCH INJURY

This is a minimal risk study, and the research team and the study doctor have taken steps to minimize your risks for taking part in this study. Even so, you may still have problems or side effects. Please tell your study doctor any injuries, side effects, or other problems that you have during or after the study as soon as possible. Water is generally recognized as safe food substance

and consumption of oxygenated water is expected to be safe as well.

You do not waive any of your legal rights by signing this form, nor do you release the Sponsor, study doctor, study staff, or study site from liability for mistakes.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this research study is your choice. You are encouraged to ask your study doctor questions at any time during the study. Make sure that all your questions are answered to your satisfaction, and you are fully aware and comfortable in the research endeavor.

Taking part in this study is voluntary. You can refuse to take part right now or can stop taking part at any time. Deciding not to take part or deciding to leave the study later will not result in any penalty or any loss of benefits to which you are otherwise entitled.

If you withdraw from the study, no new data about you will be collected for study purposes. The study doctor will inform you whether he/she intends to either: (1) retain and analyze already collected data relating to you up to the time of your withdrawal; or (2) honor your request that your data be destroyed or excluded from any analysis.

Your participation in this study may be stopped at any time by the study doctor, the Institutional Review Board (IRB), regulatory authorities, or the sponsor without your consent for any of the following reasons:

- if it is in your best interest
- you do not consent to participate in the study
- you do not continue to meet the study requirements
- for any other safety reason

You will be given a copy of this signed and dated consent form.

If we learn anything during the study that we think you should know about,

we will contact you.

By signing this consent form, you neither waive your legal rights nor relieve the study doctor(s), sponsor(s) or involved institutions from their legal and professional responsibilities.

CONTACTS

You may ask questions about this consent form or the study at any time. If you have any questions, concerns, or complaints about the study or if you feel you may have been harmed by taking part in this study, you can contact the Principal Investigator listed on Page 1.

An institutional review board (IRB) is an independent committee established to help protect the rights and welfare of research participants. Salus IRB is the IRB for this study. If you have any questions, concerns, or complaints about your rights as a research participant or regarding this research study, or if you wish to speak to someone other than the research staff, as well as situations in which the research staff cannot be reached, please contact:

Name: Salus IRB

Email: subject@salusirb.com

Phone: 1-800-472-3241

Please reference the following study number when contacting Salus: 25062.

CONFIDENTIALITY

Your personal health information will be protected according to state and federal laws. All reasonable steps will be taken to ensure confidentiality. Records of your participation in this study will be held as confidentially as possible except when sharing the information is required by law or as described in this informed consent form.

The United States government has issued a rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your protected health information (PHI). The document you are reading, called an “Authorization,” explains how your PHI will be used and disclosed (shared) for purposes of the research study and describes your rights with respect to such information.

The study doctor will use your initials and assign a code number to your information that is shared with the sponsor. The sponsor and its representatives (which include companies that are contracted by the sponsor to perform services for the study) may review or copy your protected health information at the study site. Regulatory authorities and the Institutional Review Board may also review or copy your information to make sure that the study is done properly or for other purposes required by law.

If you do not give your authorization to use protected health information, you cannot be in this study. By signing this form, you are agreeing to allow the study doctor and their team to use your protected health information to carry out and evaluate this study and to check that the study is being done properly. You also allow the study doctor to share your protected health information with:

- The sponsor, its representatives and collaborators
- Salus Institutional Review Board (IRB)
- Other regulatory agencies

Your privacy will be protected to the maximum level possible. However, absolute confidentiality cannot be guaranteed. When the results of this study are published or presented at scientific meetings, only data will be presented without identifying you.

CONSENT

I have read the information in the consent form. I have had the chance to ask questions about this study and reflect and consult with others as needed. I agree to participate in this study. By signing and dating this consent form, I am not giving up any of my legal rights. I will be given a signed and dated copy of this consent form.

_____ _____

SIGNATURE OF THE PARTICIPANT DATE

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PRINTED NAME OF THE PARTICIPANT

ATTESTATION

I have fully and carefully explained the study to the participant and confirm that, to the best of my knowledge, he/she clearly understands the nature of the study, and the risks and benefits of taking part in it.

I confirm that I gave them all opportunities to ask questions about the study, and that I answered all the questions they asked correctly and to the best of my ability.

I confirm that the subject provided consent freely and voluntarily. A copy of this consent form will be given to the subject.

_____ _____

SIGNATURE OF THE PERSON CONDUCTING INFORMED CONSENT DISCUSSION DATE

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PRINTED NAME OF THE PERSON CONDUCTING INFORMED CONSENT DISCUSSION