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Chiang Mai University

# Project Proposal

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# Executive Summary

## Objective

To seek approval from the Ethical Review Board for hosting clinical trials for the purpose of determine whether Oral Oxygen Therapy (OOT) is a safe and effective complementary treatment for patients inflicted with cancer. Approval is required in order to protect the rights of the human participants in this trial.

## Goals

Successful cancer treatment is often contingent on a combination of Western (contemporary), complementary (alternative) and breakthrough (not yet proven, as in the case of new technology) treatment methodologies. To achieve acceptance of any new treatment, carefully conducted clinical trials are the fastest and safest way to prove results that they work for people. Oral Oxygen Therapy is a combination of Western, complementary and breakthrough treatments. *Clinic trials are required to prove OOT's efficacy (or non-efficacy) and elicit informed opinions within the scientific and medical communities.*

## Reasoning for a Clinical Trial: Overview of Purpose

Oral Oxygen Therapy is administered to trial participants by ingesting oxygen-infused mineral water. Oxygen partial pressure ( $pO_2$ ) is measured to determine the relationship between the oxygen enriched water and the level of physically solved oxygen in the blood.

As humans grow older, the amount of  $pO_2$  decreases and the tissues of the human organism experience oxygen deficiency. A deficient oxygen uptake can cause severe and destructive processing in humans and other organisms. An optimal oxygen uptake is



necessary to maintain the bio reactions of the body for a healthy life. Consequently, oxygen saturation of the blood and  $pO_2$  play a decisive role.

In 1992 The Institute of Anesthesiology at the Johannes-Guenberg University in Mainz, Germany published the following results to determine the amount of  $pO_2$  in venous blood before and after a per-oral oxygen treatment of 330ml of oxygenated bottled water with an oxygen content of approximately 45mg/l.

Oxygen Partial Pressure Chart						
Parameter	Before	After 5 Mins	After 10 Mins	After 15 Mins	After 20 Mins	After 30 Mins
<b>T</b>	37°C	37°C	37°C	37°C	37°C	37°C
<b>Hb</b>	15 Gr%	15 Gr%	15 Gr%	15 Gr%	15 Gr%	15 Gr%
<b><math>pO_2</math></b>	19.5 mmHG	<b>33.8 mmHG</b>	<b>31.0 mmHG</b>	<b>30.0 mmHG</b>	<b>29.5 mmHG</b>	<b>28.0 mmHG</b>

Past results indicate that the absorption of oxygenated water begins in the mouth tissue and along the gastrointestinal tract. About 5 minutes after drinking oxygen enriched water, an increase of the  $pO_2$  value is observed in venous blood. In contrast to oxygen administered as a gas into the lungs, the effect of oxygen applied in an aqueous solution lasts for several hours. Even after 3 to 4 hours, an elevated oxygen content can be observed in the blood.

In a clinic trial, treatment results are compared to the initial baseline test through standardized carcinoma testing (e.g. a biopsy or cytology). Measuring the oxygen concentration in venous blood and within inflicted cancer cells is also a possibility.

### Previous Support for the Use of OTT in Clinical Trials

Oral Oxygen Therapy as an innovation in medicine and biology was developed for the first time in 1970 by Prof. Dr. A. Pakdaman, M.D. The therapy was first introduced in Germany in 1988 for its promising prospects for treating a variety of medical conditions.



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Oxygen enriched water has been applied in nutritional, clinical and research medicine to treat cellular hypoxia associated with chemotherapy, radiation and post-operative stress syndrome. Studies also indicate that the therapy improves blood pressure, immune system function and symptoms associated with energy deficiency.

### **Oncological Support in Clinical Trials**

1. The effects of Oral Oxygen Therapy in the therapy of head and neck carcinomas were measured by  $pO_2$  histography in 1994 by Eble, Lahr, Wannemacher in their oncological study "Oxygen tension distribution in head and neck carcinomas after peroral-oxygen therapy."
2. A 20 patient study, "Deutscher Kongress fur Radio-Onkologie, Strahlen-Biologi und Medi-Physik," Eble (1996) reported the results of those who had been treated previously by radiotherapy against lymphogene metastasized mount bottom and pharynx carcinomas.  $pO_2$  measurements wer carried out before and 5 minutes after treatment with 300ml oxygenated water (60mg  $O_2$ /l). A  $pO_2$  increase in the blood could be detected 5 minutes postprandial. After further examinations, increased tumor oxygenation was detected.
3. In 1998 32 patients with previous treatment by surgery, radiation and/or chemotherapy received additional therapies of pharmacological doses of sodium selenite and oral oxygen. Results included slight improvements of their general condition and the decrease in symptoms such as nausea, emesis, headache, vertigo, unsteady gait, speech disorders and Jacksonian seizures.
4. A case study in Thailand was reported on by Apichana Kovindha, M.D., Associate Professor in Rehabilitation Medicine at the Faculty of Medicine, Chiang Mai University on June 1st, 2011. A cancer patient was reporting high levels of liver enzymes and also carbon dioxide levels in her blood making her unfit to receive continued chemotherapy. After a couple of day of administration of mineral (Papae) water infused with  $O_2$ , she recovered and became active enough to resume house chores. Her liver enzymes and



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carbon dioxide levels returned to normal and CT scans showed no indication of the tumor previously measured at 3cm in diameter. Dr. Kovindha's conclusion was that the effectiveness of the oxygenated mineral water should be put into clinic trial.

### **Clinical Trial Protocol to be determined**

- 1.) Type of trial (e.g. the controls, placebo, blind or double-blind)
- 2.) Types of people who may participate in the trial including the selection criteria and number of people required.
- 3.) Timings for the trial: including the overall length of the study, time for participation, the schedule of tests, procedures, dosages and time for extended follow-up to monitor patient health and to determine the safety and effectiveness of the treatment (including peer review.)
- 4.) Methodology for acquiring baseline test in the selected participants.
- 5.) Methodology for obtaining followup results from the participants.
- 6.) Analysis of results that includes all data from the participants in the group.
- 7.) Presentation, peer review and recommendations from the results.

### **Why is the OOT technology Special?**

Infusing water with O<sub>2</sub> effectively requires technology to lower water temperature, put water under pressure and inject oxygen in the form of micro-bubbles. Lower temperature water holds a higher concentration of oxygen. Once the bubbles enter the water, the high pressure allows them to dissolve into the water in high concentration nano-bubbles. Recent Japanese research indicates the occurrence of increased in ion concentrations around the gas-water interface. Negative ions are known to effectively promote growth, stabilize the autonomic nerves, promote recovery from fatigue, relax blood vessels,



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decrease pulse and support good heart function, ease respiration, aid the excretion of nitrogen through urine, move blood to basicity and strengthen bone.

## Conclusion

Technological innovation is often the bar used to measure the progress of civilization. One such indicator is the alleviation of disease and the promotion of health. In order to justify the promotion and acceptance of new technology in the application of personal health, establishing a clinic trial is the first step. Within this document is presented information to make an informed decision about the establishment of such a clinic trial. A safe, effective, efficient and ethical trial by educated and experienced individuals within the field of this study is key to success. Patient well-being is the first and foremost importance in the proposed clinical trial. Moreover, there are no known side-effects from consuming oxygenated water.

## Attachments

1. OOT Report, Pakdaman, Germany
2. Dr. Kovinda, Letter, Thailand
3. Water Test Lab Report, Thailand
4. Dr. Takahashi Micro-bubble Report, Japan
5. JRH NanoBubble Report, Thailand
- 6.