

STUDY 1

Medical Research Summary (Human Study)

TITLE	ORAL OXYGEN THERAPY In combination with the usual lines of treatment used in COPD and IPF
FACILITY	University of Cairo, Medical School Respiratory Intensive Care Unit, Kasr Elini Hospital
DATE	January, 2000

Summary

- * 50 patients suffering from hypoxaemia were included in this study
- * 28 patients with COPD (Chronic Obstructive Pulmonary Disease)
- * 22 patients with IPF (Interstitial Pulmonary Fibrosis)
- * 27 were male
- * 23 were female

Patients were given

- AQUAGEN®
- treated with standard therapy (but not ordinary gaseous oxygen)
- combination of AQUAGEN®, and standard therapy (without gaseous oxygen).

Results

- * Significant improvement of the partial pressure of oxygen (blood-oxygen level, Pao₂) in both COPD and IPF patients (**Good results**)
- * Significant reduction of blood-carbon dioxide level (Paco₂) in both COPD and IPF (**Good**)
- * Expiration force improved in COPD patients when a bronchodilator was used with AQUAGEN®. (**Good**)

Conclusions and Recommendations

- * AQUAGEN®, was helpful in the management of hypoxaemia in COPD and IPF patients.
- * The use of AQUAGEN®, was synergistic when using standard treatment.
- * Further studies should be conducted on AQUAGEN®

STUDY 2

Medical Research Summary (Human Study)

TITLE VALUE OF STABILIZED OXYGEN (AQUAGEN®)
In the treatment of hypoxemia

FACILITY University Medical School

DATE Published April, 2001
The Journal of Chest Diseases and Tuberculosis

Summary

- * 60 patients suffering from hypoxemia were included in this study
- * 30 patients with IPF (Interstitial Pulmonary Fibrosis)
- * 30 patients with COPD (Chronic Obstructive Pulmonary Disease)

Results

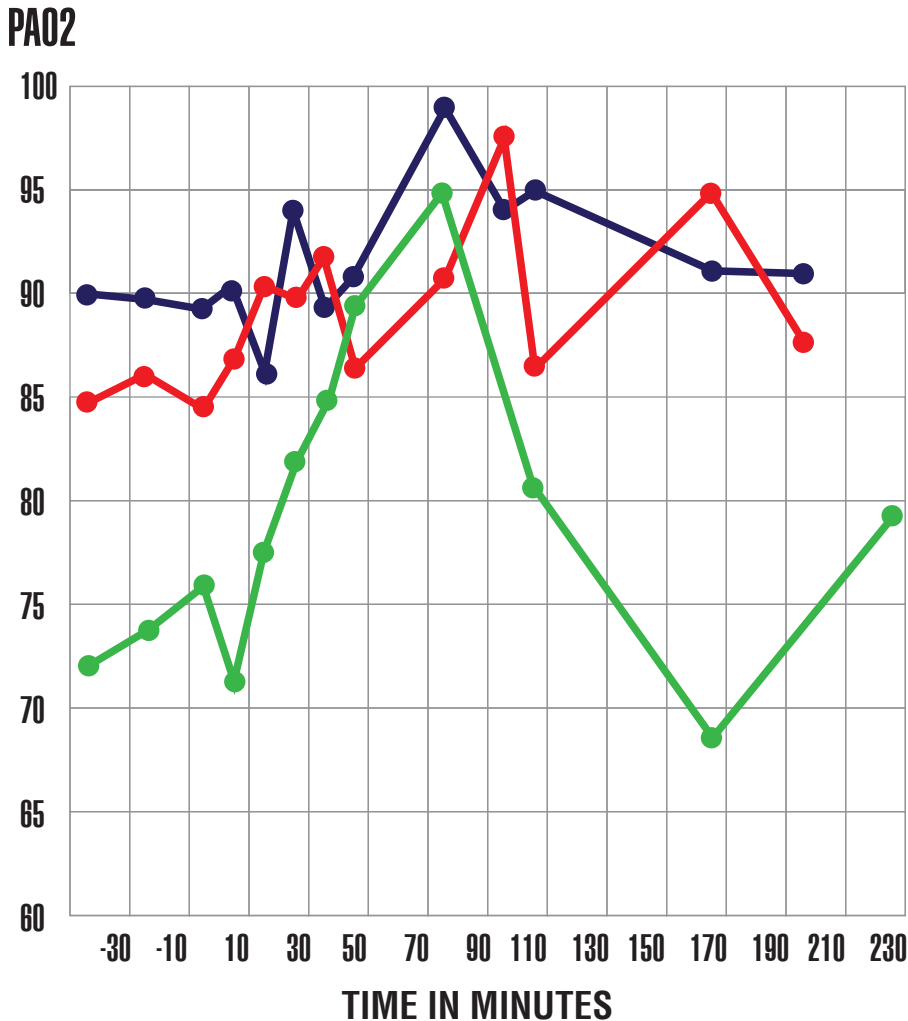
- * IPF: highly significant increase of blood-oxygen level (Pao₂) over baseline level
- * IPF: after two week stoppage, the oxygen level was still significantly higher than baseline
- * COPD: highly significant increase of blood-oxygen level over baseline level
- * COPD: after two week stoppage, there was only an insignificant decrease in the oxygen level
- * The control groups without AQUAGEN® continued to have low Pao₂
- * No adverse side effects were noticed
- * Well tolerated by all patients without exception

Conclusions and Recommendations

- * AQUAGEN® could be a good replacement for home use of oxygen tanks
- * Can be used safely with patients having renal or liver impairments
- * Can be an alternative to standard hypoxemia therapy
- * Increases tissue oxygenation and improves aerobic oxidation.....
- * Thus, resulting in better use of nutrients, yielding more energy, improved mental concentration, and improve quality of life
- * Easy to use

THE SUNTRORY STUDY

Suntory International performed this independent study to determine whether the partial pressure of oxygen in arterial blood (PaO₂) in the forearm after rest would change following the oral consumption of Aquagen®. Three healthy males were tested before and after consuming Aquagen® over a period of 240 minutes. The dosage was 6 mL of Aquagen® per person.



Suntory's conclusion

"Each subject's partial pressure of oxygen was relatively stable prior to Aquagen® consumption, but then rose immediately after Aquagen® consumption. The partial pressure of oxygen peaked 90 to 120 minutes after Aquagen® consumption, after which it gradually dropped, eventually reaching its pre-Aquagen® consumption level. In a subject with a particularly low baseline, a significant increase was detected."

Source: Suntory International of Japan (May 2nd, 1996)

ANTIMICROBIAL, CHEMICAL ASSAY AND OXYGEN TEST REPORTS SUMMARY (JANUARY, 1996)

1. Nelson Laboratories, Inc. of Salt Lake City, UT completed its Antimicrobial Preservative Effect Test (Lab Number 72984B) for Aquagen®, the Stabilized Oxygen Supplement (Batch SL6) at 100% concentration on March 13, 1995 against the following organisms:

Bacteria	Staphylococcus Aureas (ATCC 6538); Pseudomonas Aeruginosa (ATCC 9027); Escherichia Coli (ATCC 8739)
Yeast	Candida Albicans (ATCC 10231)
Mold	Aspergillus Niger (ATCC 16404)

Organisms were assayed for surviving organisms after 0 hours (immediately after application of Aquagen®) and at 7, 14, 21 and 28 days. According to U.S. Pharmacopeia, a preservative is considered effective if the number of bacteria recovered is not more than 0.1% of the initial concentration by the 14th day; the number of molds and yeasts recovered per ml remains at or below the initial concentration during the first 14 days; the number of organisms per ml remains at or below the designated levels during the remainder of the 28 day period.

Nelson Labs reported

"The test product reduced all of the challenge organisms below the detectable limits at time 0 sample interval. No organisms were recovered from the product throughout the remainder of the test. The test product (Aquagen®) meets the USP requirements for an effective Antimicrobial preservative against the standard test organisms."

2. Nelson Laboratories, Inc. of Salt Lake City completed its Modified Antimicrobial Preservative Effect Test (Lab Number 75705) for Aquagen®, the Stabilized Oxygen Supplement (Batch SL6) at 50% concentration on April 10, 1995 (Laboratory Number 75705), protocol Number 950833-1) against the following organisms:

Bacteria	Staphylococcus Aureas (ATCC 6538); Pseudomonas Aeruginosa (ATCC 9027); Escherichia Coli (ATCC 8739)
Yeast	Candida Albicans (ATCC 10231)
Mold	Aspergillus Niger (ATCC 16404); Aspergillus Flavus (ATCC 9643)

Organisms were assayed for surviving organisms after 0 hours (immediately after application of Aquagen®) and at 24 hours. The table below is Nelson Lab's summary which indicates that all four organisms were effectively controlled at both 0 hour and at 24 hours 99.9%

Test Organism		Sample Test Time Elapsed		
		Control	0 Hours	24 Hours
Staphylococcus Aureus (ATCC 6538)	CFU/mL	1.193.333	< 10	< 10
	Percent Reduction	N/A	99.9%	99.9%
Pseudomonas Aeruginosa (ATCC 9027)	CFU/mL	3.873.333	< 10	< 10
	Percent Reduction	N/A	99.9%	99.9%
Esheriria Coli (ATCC 8739)	CFU/mL	1.303.333	< 10	< 10
	Percent Reduction	N/A	99.9%	99.9%
Candida Albicans (ATCC 10231)	CFU/mL	1.180.000	< 10	< 10
	Percent Reduction	N/A	99.9%	99.9%
Aspergillus Niger (ATCC 16404)	CFU/mL	297.333	< 10	< 10
	Percent Reduction	N/A	99.5%	99.9%
Aspergillus Flavus (ATCC 9643)	CFU/mL	1.742.333	< 10	< 10
	Percent Reduction	N/A	99.5%	99.9%

3. Dr. Joseph Montelcalvo, Jr., PhD, of Central Coast Consulting, completed a preliminary study of the Antimicrobial effect of a 1% solution of Aquagen® on Cat's Claw (herb) on July 25th, 1995. He wrote: "We find that Aquagen® is very effective when used as a sanitizing disinfectant on the Cat's Claw. The results of this study show that on average the 1% SL-12-1 product showed a reduction of 85.7% of total molds on the powder and 82.9% reduction on the chips...Based on these findings, Aquagen® shows great promise as a sanitizing agent for herbs, spices and other agricultural products where a significant reduction in mold colony units is required to enhance / maintain quality, reduce spoilage and extend shelf life."

4. Dr. Joseph Montelcalvo, Jr., PhD, of Central Coast Consulting, completed a second study of the Antimicrobial effect of a 3.5% solution of Aquagen® on Cat's Claw (herb) chips on October 12, 1995. He concluded: "Aquagen® showed a percent mold reduction of 85.56% and 94.23% after 5 and 15 minutes respectively. Yeast reduction as a function of Aquagen® treatment was 88.19% and 91.1% after 5 and 15 minutes of treatment. These results clearly indicate that Aquagen® treatment at 3.5% level can reduce over 94% of the level of mold and over 91% of yeast cell contamination...On the basis of the data obtained from this study, Aquagen® is very effective and its effectiveness should be relatively the same on agricultural products such as apples, pears, grapes, carrots, etc. Therefore, there is great need in the industry to find a sanitizing compound that could take the place of chlorine (Chlorine Dioxide). Aquagen® shows promise based on the available data and information provided to me to date."

Chemical Assay Tests

- 1. Chemtech Analytical Laboratory in Salt Lake City, UT** completed a certificate of analysis (Lab #U011783) on ten drops of Aquagen® (Batch SL18B) in 8 ounces of distilled water on July 27th, 1994. The lab's analysis determined that the TDS level in mg/L was 202 with almost every parameter test near or below the lab's minimum detection levels. Only Chloride (at 145 ppm or mg/L). Nothing on the lab analysis approaches FDA's or EPA's maximum contaminate levels or is an unapproved constituent in a food supplement.
- 2. Pace Incorporated Environmental Laboratories in Camarillo, CA** completed a laboratory analysis (Lab # CK-5540-1) on a 100% solution of Aquagen® on November 15, 1994. The lab determined that Aquagen® contains no sodium chlorite (NaClO₂) no any chlorite (ClO₂).
- 3. Pace Incorporated Environmental Laboratories in Camarillo, CA** completed a laboratory analysis (Lab # CK-6317-4) on a 100% solution of Aquagen® on January 4th, 1994. It was determined that Aquagen® contains trace nutritional minerals including Calcium (52 mg/L) and magnesium (23 mg/L).
- 4. John H. MacDonald, Ph.D, Senior Scientist at USANA, Inc. in Salt Lake City, UT**, analyzed Chemtech Aquagen® Assay Report #U011783-SL-18_B sampled 7/21/94 and determined: "I can find no substance with levels high enough to indicate toxicity to anyone consuming Aquagen®. The sodium levels at only 9.24 ppm are well below the recommended daily reference values determined by the U.S. Government. Toxic metals (lead, mercury & arsenic) are virtually undetectable as are nitrate levels and other trace minerals. Aquagen®, in its current formulation, is totally safe to the human body.

FDA Review

M. Val Miller, Attorney at Law, specialist in FDA regulations and former Associate Chief Counsel for the FDA in Washington, D.C. wrote: "Clearly, Aquagen International's product is subject to the conditions of the D.S.H.E.A. (Dietary and Supplement Health Education Act). By definition, a dietary supplement means, 'a product intended to supplement the diet by increasing the total dietary intake that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical...' (See 21 USC p. 321 et. seq.) Aquagen® the stabilized oxygen supplement is, as a matter of law, a dietary supplement."

Thomas L. Sawyer, Director, Compliance Branch, Department of Health and Human Services, Public Health Service Food and Drug Administration, wrote on October 5, 1995: "We have reviewed your revised package label, container label and promotional material submitted and have the following comments. The product Aquagen® is a dietary supplement as defined in Section 201(f) of the Federal Food, Drug, and Cosmetic Act (the Act)."