

# Halotherapy

Dry saline aerosol inhalation

“Sodium chloride aerosol inhalation improves rheological properties of the bronchial contents, decreases edema of bronchial mucosa and contributes to functioning of cilia epithelium. It has a bactericidal action, enhancing functioning alveolar macrophages.” \*

\*Chervinskaya AV, Zilber NA. Halotherapy for treatment of respiratory diseases. *Journal of Aerosol Medicine* 1995 Fall;8(3):221-232.

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## FORMS

- Informed consent to treatment form
- Referral form

## Therapy name

Salt/Speleo/Halotherapy

## Background on Speleotherapy and Halotherapy

Speleotherapy or underground climatotherapy is a complementary/alternative treatment for respiratory problems used widely in Eastern Europe and Russia. It involves spending 2-3 hours a day underground in subterranean caves or salt mines over a 2-3 month period. Speleotherapy has been recognized as an effective drug-free treatment method for certain types of chronic pulmonary diseases, such as asthma and chronic obstructive pulmonary disease (COPD)<sup>1</sup>. Based on the therapeutic action produced by cave air saturated with particles of rock salt, this treatment has been shown to provide substantial benefits to patients with respiratory diseases<sup>2</sup>.

Published studies suggest that the efficacy of Speleotherapy may be related to its direct immunological effects<sup>3</sup>, either by increasing the number and activity of T-lymphocytes or altering complement levels.

Halotherapy (HT) is a mode of treatment in a controlled air medium that simulates the natural salt cave microclimate. HT is performed in a special room with salt-coated walls and floor – the ‘Halochamber’. Dry sodium chloride aerosol containing particles of 1-5 µm in size is produced by a special nebulizer and released into the Halochamber. The effect of HT was evaluated in 124 patients with various types of respiratory diseases (bronchial asthma, chronic obstructive and non-obstructive bronchitis, bronchiectasis, cystic fibrosis) in a placebo-controlled clinical trial. HT resulted in significant clinical improvements as measured by various lung function tests (flow-volume loop parameters, body plethysmography, bronchial resistance) compared to placebo<sup>6</sup>. Other studies have reported similar benefits in patients with chronic pulmonary disease<sup>7,8,9</sup>. The Russian Ministry of Health approved the Halocomplex Chamber as a medical device in 1995. Most of the published work on Halotherapy has appeared in Russian journals and publications.

<sup>1</sup>Horvath T. Speleotherapy: a special kind of climatotherapy, its role in respiratory rehabilitation. *Int Rehabil Med* 1986;8(2):90-92.

<sup>2</sup>Karakoca V, Demir G, Kisacik G et al. Speleotherapy in asthma and allergic diseases. *Clinical and Experimental Allergy* 1995;25: 666-67.

<sup>3</sup>Abdullaev AA, Gadzhiev KM, Eiubova AA. (The efficacy of Speleotherapy in salt mines in children with bronchial asthma based on the data from immediate and late observations). *Vopr Kurortol Fizioter Lech Fiz Kult* 1993 Sep-Oct;(5):25-8.

<sup>4</sup>Simonka-luM, Chonka-la V, Pop IL. Effect of the microclimate of salt mines on T- and B-lymphocytes function in bronchial asthma patients. *Vrach Delo* 1989; 3: 57-9.

<sup>5</sup> Mohap J, Bohac S, Weigl, E. Values of selected immunological parameters before and after Speleotherapy. *Acta Univ Palacki Olomuc Fac Med* 1991;131:197-211.

<sup>6</sup> Chervinskaya AV, Zilber NA. Halotherapy for treatment of respiratory diseases. *J Aerosol Med* 1995 Fall;8(3):221-232.

<sup>7</sup> P.P.Gorbenko, Adamova IV, Sinitsyna TM. Bronchial hyperreactivity to the inhalation of hypo and hyperosmolar aerosols and its correction by Halotherapy. Ministry of Public Health of the Russian Federation, Russian Pneumological Scientific Society Pulmonology, 1993;3(2).

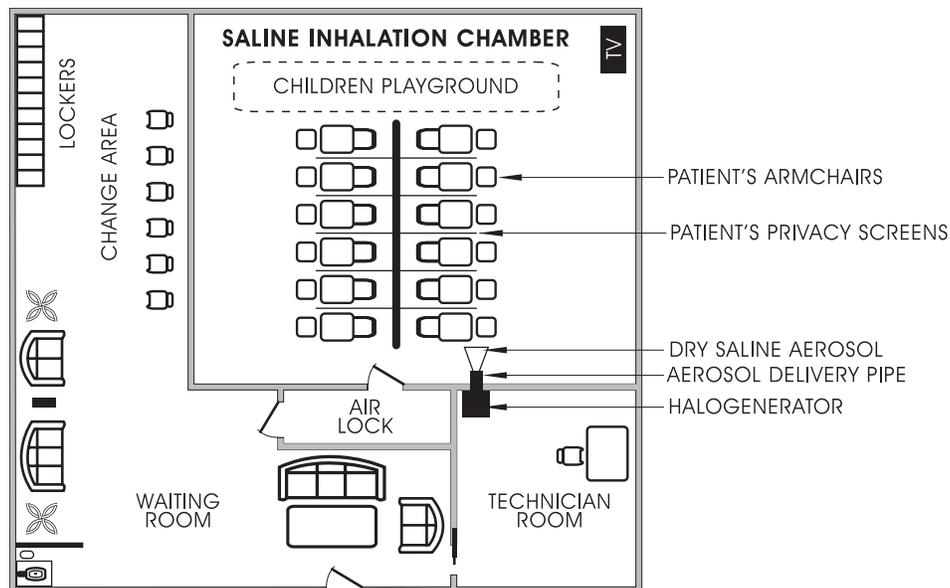
<sup>8</sup> E.N.Semochkin, V.P. Silvestrov, V.N. Surovnikov. Halotherapy: Complex treatment in out-patients with breathing (respiratory tract) pathologies. Kremlin Medicine. *Clinical Herald* 1999;3.

<sup>9</sup> G.A.Norvaisa, D.Noreikiene. Halotherapy in management of endogenous bronchial asthma. Center for Halotherapy, Pulmonology Department, Hospital Red Cross, Klaipeda, Lithuania. Annual meeting, Interasthma, Palanga, Lithuania, May 28-30, 1999.

## Medical Device Classification

Through correspondence with the “Speleotherapy” Clinic in April 2002, Health Canada classified the Halocomplex Aerosol Chamber as a class 1 device by Rule 7(1) and Rule 12 of the Canadian Medical Device Regulations.

## The Technology



General layout of the dry saline aerosol inhalation chamber

The Halocomplex consists of a speleoclimatic chamber (walls and floor are covered with rock salt) with the addition of a halogenerator. The special salt covering on the walls and floor acts as a buffer for air moisture and helps maintain the environmental aseptic properties.

Dry sodium chloride aerosol containing particles of 1-5  $\mu\text{m}$  in size is produced in this room by a special nebulizer, the halogenerator; the device which pushes air containing this aerosol into the chamber. The halogenerator is situated in an interconnecting room and brings a flow of clean, dry air, saturated with highly dispersed negatively charged particles of sodium chloride into the therapeutic room.

The halogenerator has a microprocessor that monitors and maintains the temperature, relative humidity and mass concentration of aerosol in the chamber. In contrast, Speleotherapy relies solely on the natural salt environment.

The advantages of Halotherapy are the provision of a specified concentration of dry salt aerosol under controlled conditions of temperature and relative humidity, while regulating the size and speed of the dry sodium aerosol particles. The halocomplex controls and maintains the concentration of highly dispersed aerosol at four pre-set levels (level I to IV), providing a concentration of dry sodium chloride between 1 to 16  $\text{mg}/\text{m}^3$ .

These parameters are found in the natural environments of different Speleotherapy medical centers, which are located in natural salt caves and mines throughout Eastern Europe.

### **Fractions of dry sodium chloride aerosol in the Halochamber (according to the data of optical devices)**

| Size of particles, $\mu\text{m}$ | Fractions (%)  |
|----------------------------------|----------------|
| 1-2                              | $35.4 \pm 2.1$ |
| 2-5                              | $61.8 \pm 3.3$ |
| 5-10                             | $2.8 \pm 0.4$  |
| >10                              | 0.003          |

This environment has stable humidity (relative air humidity 40-60%) and stable air temperature (18-24°C). These parameters create comfortable conditions for patients and promote a stable aerosol environment.

A stable hypoallergenic, hypobacterial environment is maintained in the therapeutic room. The assessment of the microbial contamination during a session of Halotherapy proves that 1 $\text{m}^3$  contains from 90 - 200 saprophytic microorganisms (according to WHO standards on air sterility, 1 $\text{m}^3$  should contain less than 300 microbial bodies). Microflora content returns to its initial level 10-20 minutes after the session is completed.

## Generic Name

Dry saline aerosol inhalation in a microclimate chamber

## Indications for Use

### To relieve the symptoms of the following conditions:

- ◆ chronic bronchitis
- ◆ breathlessness, chest tightness
- ◆ pneumonia after acute stage
- ◆ bronchiectatic disease
- ◆ cough (particularly at night or after exercise)
- ◆ wheezing
- ◆ smokers' cough (including secondary smoke)
- ◆ cough with viscous sputum, discharging with difficulties
- ◆ dry, paroxysmal cough with distant rales
- ◆ dry rales (mostly with low tone) changing its localization during auscultation
- ◆ mucus plugs
- ◆ mucosal edema
- ◆ colds and influenza
- ◆ sinusitis
- ◆ rhinitis and respiratory allergies
- ◆ allergies to industrial and household pollutants
- ◆ frequent acute disorders of respiratory tract
- ◆ respiratory infections
- ◆ rhinosinusopathy
- ◆ tonsillitis
- ◆ pharyngitis
- ◆ multi-chemical sensitivity syndrome
- ◆ eczema, psoriasis
- ◆ postoperative rehabilitation and recovery (aesthetic & sinus surgery)

## Mechanisms of Action

The main effective factor is a curative breathing environment, which is saturated with dry sodium chloride aerosol at a mass concentration varying from 1-16 mg/m<sup>3</sup> with a particle size of 1-5 μm. Particle size is optimal for penetration in all sections of the respiratory tract. Dry sodium chloride aerosol has a considerable level of negative charge of the particles (6-10 nK/m<sup>3</sup>). The inner surfaces of airways have a slight positive charge. Negatively charged particles of dry sodium chloride aerosol move in the lumen of the respiratory tract and settle more intensively compared to neutral particles. In addition, the negative charge increases aerosol stability. Thus dry aerosol action is much more effective than one that is moist.

The use of dry aerosol allows the creation of the optimal temperature and humidity parameters in the curative chamber, thus avoiding respiratory tract mucus edema and bronchial spasm; common reactions in patients when moist aerosols are used. Furthermore, the dose of sodium chloride received by the patient within a 1 hour Halotherapy session is less than the dose received while inhaling moist sodium chloride aerosol.

### **The positive effect of Halotherapy could be explained in the following way:**

One of the pathogenesis mechanisms of obstructive lung diseases is the mucocellular clearance disturbance. Sodium chloride aerosol improves rheological properties of the airway's content and normalizes mucocellular clearance. Sodium chloride is necessary for normal functioning of the bronchial ciliated epithelium, whereas the sodium chloride content in the bronchial secretion of patients with chronic lung diseases decreases. Due to the aerosol's curative influence, the beneficial effects in improving respiratory tract drainage function are evident during Halotherapy. Relief of sputum expectoration, reduction of sputum viscosity, relief of coughing and positive changes in the auscultatory picture of the lungs are notable.

Sodium chloride aerosol provides bactericidal and bacteriostatic effect on respiratory tract micro flora and stimulates alveolar macrophage reactivity, facilitating the increase of phagocyte elements and their activity. Cytobacteriological research of bronchial and nasopharyngeal content of patients with asthma, chronic obstructive bronchitis and cystic fibrosis demonstrate the fact that Halotherapy promotes the reduction of neutrophils and pathogenic microorganisms and increases alveolar macrophages. Its inhibitory effect on growth and vital capability of microorganisms is accompanied by loss of their pathogenic properties and by adaptation to changed conditions. This adaptation, due to the loss of fluid, leads to the enhancement of their hydrophobic properties, facilitating attachment to epithelial cells. However, the activation of microbial adhesion does not occur due to the increase of epithelial cells' electrophysiological functional activity. Moreover, the colonization resistance of epithelial cells is enhanced under the effect of dry sodium chloride aerosol. This indicates its favorable action on the protective properties of respiratory tract cells and activation of non-specific body defense.

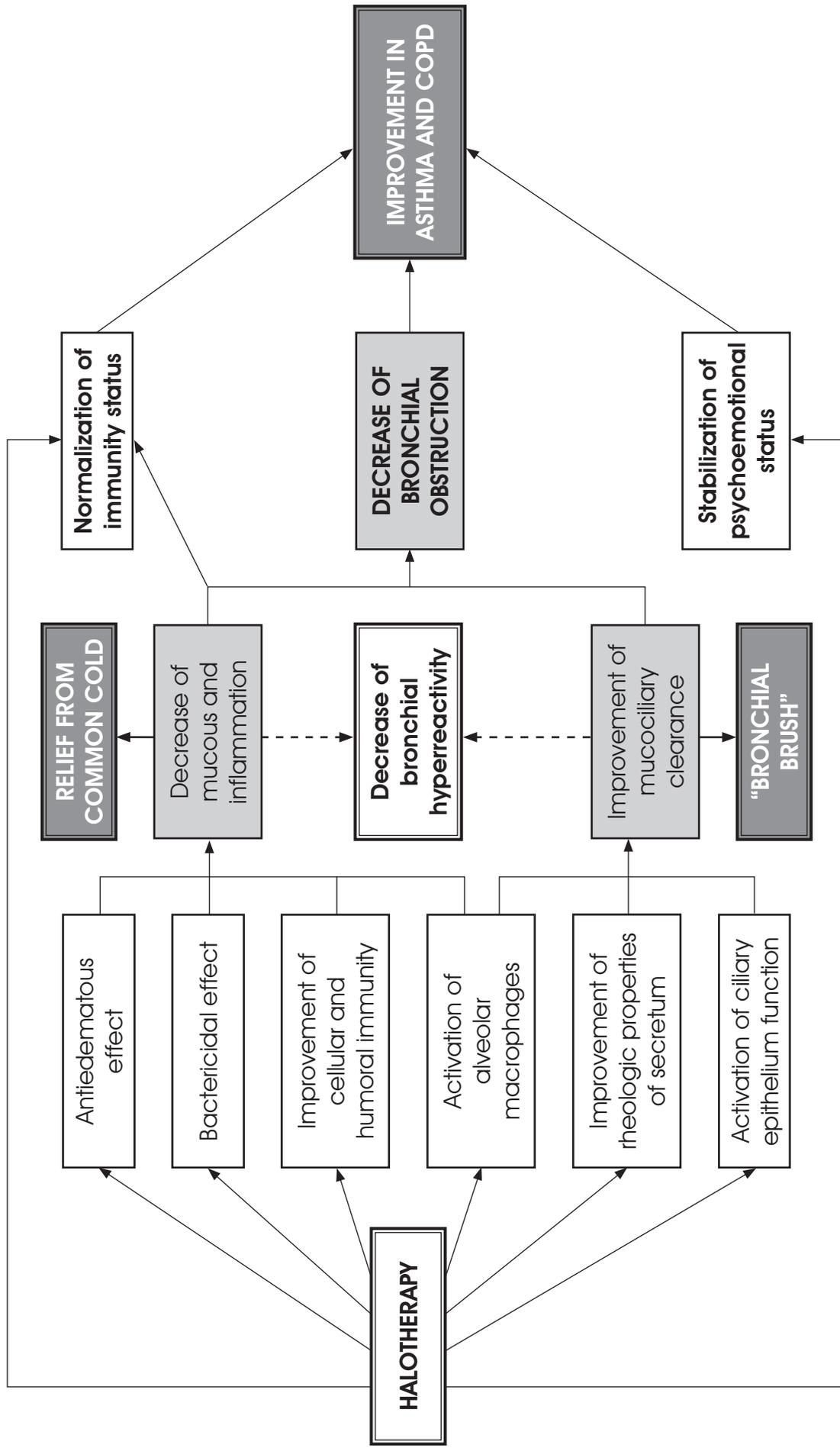
Superficial skin autoflora of most of the patients normalizes after Halotherapy sessions. Halotherapy positively affects humoral and cellular immunity of patients with chronic lung diseases. The reduction of IgE levels after Halotherapy in patients with asthma is especially important.

Optimal temperature and humidity, hypoallergenic and hypobacterial air medium are maintained in the Halochamber. Breaking patient contact with pathogenic external air factors has an additional positive influence on the organism.

**The mechanisms of action** of Halotherapy are manifold:

- ◆ mucolytic
- ◆ antibacterial
- ◆ antiinflammatory
- ◆ immunomodulating
- ◆ hyposensitizing

# MECHANISMS OF HALOTHERAPY ACTION\*



\* Ponomarenko G.N., Chervinskaya A.V., Kononov S.I. **Inhalation Therapy.** St. Petersburg: SLP, 1998. P. 205

Annual meeting, "Interastma", Palanga, Lithuania, May 28-30, 1999

Abstract

## **HALOAEROSOL THERAPY IN THE REHABILITATION OF ASTHMA PATIENTS**

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The use of natural physical factors has a great significance in asthma patients' rehabilitation. The atmosphere of salt cave or mines is the main curative factor of the haloaerosol therapy (HT) method. The controlled air medium with the respirable particles of dry salt aerosol is created in an ordinary room with special equipment. Density of aerosol depends on nosology, clinical features and FEV<sub>1</sub> (0,5-1; 1-2; 3-5; 7-9 mg/m<sup>3</sup>). Other factors are comfortable temperature and humidity, and hypobacterial and allergen-free air medium.

The HT method was sanctioned by the Russian Ministry of Public Health in 1990. To study the efficacy of HT, data was collected from 15 Russian hospitals (from 1991 to 1994). We have evaluated the results of HT in 4780 adults and children with various types of pulmonary diseases. An HT course consisted of 10-20 daily procedures of 1 hour each.

The HT results were assessed by physicians on the basis of clinical symptoms, functional parameters and medication dosages with the use of standard questionnaires. HT resulted in improvement of clinical state in 85% of mild and moderate asthma cases, 75% of severe asthma cases and 97% of chronic bronchitis and bronchiectasis cases. Long-term examination of patients (for one or more years) demonstrated the effect of HT on reduction in the frequency of exacerbations and reduction in chronic symptoms.

## **Halotherapy & Hyperactivity of the Airways\***

It is known that sodium chloride aerosol is an osmolar stimulus and it can result in the hyperactivity of the airways (Schoeffel et al, 1981). The specificity of HT is the low concentration and gradual administration of dry sodium chloride aerosol (DSCA). Saline aerosol concentration in the air during a procedure depends upon the regime chosen and is about 1-16 mg/m<sup>3</sup>. For comparison, sodium chloride aerosol inhalation challenge is used for diagnosing hyperactivity of the airways. Hypotonic (less than 0.9%) or hypertonic (2-5%) solutions of sodium chloride are usually employed. When the inhalator production is 1mL per minute, 20 mg of sodium chloride (measured as a dry substance) gets into the airways during 1min of the challenge test with a 2% solution and the amount reaches 50 mg in case of a 5% solution. Compare: during a minute session of HT, 0.05 - 0.10 mg of dry sodium chloride penetrates the patient's airways when the concentration in the Halo-chamber is 5 mg/m<sup>3</sup>. Sodium chloride aerosol in low concentration does not affect the airway mucosa thus preventing any side effects. Besides, the use of dry aerosol enables the establishment of an appropriate humidity in the environment thus the adverse reactions of the airways, associated with humidification are avoided. (Linker, 1982)

\* Chervinskaya AV, Zilber NA. Halotherapy for treatment of respiratory diseases. *J Aerosol Med* 1995 Fall;8(3):221-232.

### Rare side effects

Slight skin irritation appearing as a small punctate skin rash are observed in some patients after Halotherapy sessions. These effects usually disappear after 3-5 sessions. In cases where a throat tickle occurs, gargling with boiled water is recommended. Conjunctivitis may occur due to irritation of the mucous membrane of the eye during Halotherapy sessions. It is recommended to instill eye drops (sulfacetamide solution) for 5-7 days in order to stop inflammatory process and have the patient keep their eyes closed during Halotherapy sessions.

**Drug interactions** - Not known

### Contraindications

The following are the primary contraindications:

- ◆ Acute stage of respiratory diseases
- ◆ Chronic obstructive lung diseases with the 3<sup>rd</sup> stage of chronic lung insufficiency
- ◆ Intoxication
- ◆ Cardiac insufficiency
- ◆ Bleeding
- ◆ Spitting of blood
- ◆ Hypertension in IIB stage
- ◆ All internal diseases in decompensation

Factors that increase compliance:

- ◆ This is a gentle treatment with rare temporary minor side effects (e.g. itchy skin, throat tickle)
- ◆ Treatment benefits usually last up to 12 months, sometimes longer
- ◆ There is a very pleasant environment during the treatment; patient sits in a comfortable armchair, in a spacious, cave-like room, inhaling air saturated with salt aerosol. The treatment is accompanied by relaxation music
- ◆ No additional costs are involved (e.g. supplements, etc.)
- ◆ Treatment cost is reasonable, sometimes insurable
- ◆ The clinic has health care professionals on staff to recommend the appropriate course of treatment and monitor the patient throughout the treatment process

Factors that might decrease compliance:

- ◆ Frequency of treatments; it is generally recommended to have one treatment per day for 2 weeks, although the number of patients who have them less often still benefit from the therapy

## Availability

### Formulary

- ◆ The treatment is not covered by provincial insurance or hospital formularies

### Formulation

- ◆ Four different aerosol concentrations are available (1, 2.2, 5.5 and 16 mg per cubic meter; total space of microclimate aerosol chamber is 100 cubic meters.)
- ◆ Treatment can be used for children as well as adults
- ◆ Treatment time is 60 minutes for adults and 45 minutes for children (depending on age)

## Cost

- ◆ The standard fee for a Halotherapy treatment is 35 pounds
- ◆ The introductory session is complimentary with no obligation. We offer special payment programs for lower-income families in order to make the therapy affordable to everyone
- ◆ Some of our services **are covered by extended health care plans**

## Information Sources

Chervinskaya AV, Zilber NA. Halotherapy for treatment of respiratory diseases. *J Aerosol Med* 1995 Fall;8(3):221-232.

Horvath T. Speleotherapy: a special kind of climatotherapy, its role in respiratory rehabilitation. *Int Rehabil Med* 1986;8(2):90-92.

Karakoca V, Demir G, Kisacik G et al. Speleotherapy in asthma and allergic diseases. *Clinical and Experimental Allergy* 1995;25: 666-67.

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Mohap J, Bohac S, Weigl, E. Values of selected immunological parameters before and after Speleotherapy. *Acta Univ Palacki Olomuc Fac Med* 1991;131:197-211.

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E.N.Semochkin, V.P. Silvestrov, V.N. Surovnikov. Halotherapy: Complex treatment in out-patients with breathing (respiratory tract) pathologies. Kremlin Medicine. *Clinical Herald* 1999;3.

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## Dosage and number of treatments based on Eastern European published clinical reports

| Indications  | Dosage<br>Concentrations of<br>dry saline aerosol<br>(mg per cubic meter) | The number of<br>treatments |
|--|---|-----------------------------|
| <b>Asthma ( mostly allergic etiology )</b>                             | <b>1</b>  | <b>12-14</b>                |
| <b>Asthma (mostly infection-dependant etiology)</b>                    |   |                             |
| <b>FEV<sub>1</sub>&gt;60%</b>  | <b>5.5</b>  | <b>14-18</b>                |
| <b>FEV<sub>1</sub>&lt;60%</b>  | <b>2.2</b>  | <b>18-21</b>                |
| <b>Chronic obstructive bronchitis</b>                                  |   |                             |
| <b>FEV<sub>1</sub>&gt;60%</b>  | <b>5.5</b>  | <b>14-18</b>                |
| <b>FEV<sub>1</sub>&lt;60%</b>  | <b>1</b>  | <b>18-21</b>                |
| <b>Allergic rhinitis, rhinosinusopathy</b>                             | <b>1</b>  | <b>12-14</b>                |
| <b>Chronic non-obstructive bronchitis</b>                              | <b>5.5</b>  | <b>14-18</b>                |
| <b>Chronic Recurrent bronchitis</b>                                    | <b>5.5</b>  | <b>12-14</b>                |
| <b>Smokers</b>   | <b>5.5</b>  | <b>12-14</b>                |
| <b>Acute Upper Airway Viral Infection</b>                              | <b>2.2</b>  | <b>5-7</b>                  |
| <b>Bronchiectatic disease</b>  | <b>5.5 -16</b>  | <b>20-25</b>                |
| <b>Mucoviscidosis (Cystic fibrosis)</b>                                | <b>5.5-16</b>   | <b>20-25</b>                |
| <b>Chronic Rhinitis</b>  | <b>5.5</b>  | <b>12-14</b>                |
| <b>Chronic Pharyngitis</b>   | <b>5.5</b>  | <b>12-14</b>                |
| <b>Tonsillitis (Adenoiditis )</b>                                      | <b>5.5</b>  | <b>12-14</b>                |
| <b>Chronic Sinusitis</b>   | <b>5.5</b>  | <b>12-14</b>                |
| <b>Acute Sinusitis</b>   | <b>16</b>   | <b>5</b>                    |
| <b>Atopic Dermatitis, Neuro-dermatitis</b>                             | <b>5.5</b>  | <b>12-18</b>                |
| <b>Psoriasis</b>   | <b>16</b>   | <b>12-18</b>                |
| <b>Purulent Skin Infections</b>  | <b>16</b>   | <b>12-18</b>                |
| <b>Healing of post-surgery scars</b>                                   | <b>5.5</b>  | <b>12-18</b>                |
| <b>Multi chemical sensitivity syndrome</b>                             | <b>1</b>  | <b>12-14</b>                |
| <b>Sick building syndrome</b>  | <b>1</b>  | <b>12-14</b>                |
| <b>Persons having contact with industrial and household pollutants</b> | <b>1</b>  | <b>12-14</b>                |

# INFORMED CONSENT TO HALOTHERAPY TREATMENT

I, \_\_\_\_\_, a patient of \_\_\_\_\_ (the 'Clinic') have requested Halotherapy treatment.

The nature of Halotherapy, the expected benefits, material risks, material side effects and the alternative courses of action including the likely consequences of not receiving treatment have been explained to me.

I understand the explanation and am satisfied that my questions have been answered.

I hereby acknowledge the unproven and unconventional nature of Halotherapy and have requested Halotherapy notwithstanding.

In consideration of receiving Halotherapy and further to my consent, I, a patient of the 'Clinic' hereby release the Clinic and its directors, officers, employees, agents and professional staff from all actions, causes of action, suits, claims, liability, damages and demands of any kind, whether direct, indirect, special, exemplary or consequential, including interest thereon (the "Claims") which may occur as a result of any injury including death sustained by myself or others resulting from the receipt of Halotherapy.

I agree that the relationship and the resolution of any and all disputes arising between myself and the 'Clinic' or the Health Practitioner shall be governed by and construed in accordance with the laws of United Kingdom.

I hereby acknowledge that Halotherapy will be performed in the United Kingdom and the Courts of the United Kingdom shall have jurisdiction to entertain any compliant, demand, claim or cause of action whether based on alleged breach of contract or alleged negligence arising out of Halotherapy.

I hereby agree that if I commence any such legal proceedings they will be confined to the United Kingdom and hereby irrevocably submit to exclusive jurisdiction of the Courts of the United Kingdom.

DATED this \_\_\_\_ day of \_\_\_\_\_, 20\_\_.

\_\_\_\_\_  
Signature of Patient

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Name of Patient

\_\_\_\_\_  
Name of Witness

# Request to provide Dry Saline Aerosol Inhalation

## Patient's information:

Patient's name \_\_\_\_\_

Date of birth \_\_\_\_\_

## Doctor's information:

Physician name (printed) \_\_\_\_\_

Signature \_\_\_\_\_

## Prescribed Parameters

- **Dose (concentration of dry saline aerosol in the air of the chamber)**
  - 1 mg/m<sup>3</sup>
  - 2.2 mg/m<sup>3</sup>
  - 5.5 mg/m<sup>3</sup>
  - 16 mg/m<sup>3</sup>
- **Mode of Administration - Inhaled**
- **Frequency** \_\_\_\_\_
- **The number of treatments required** \_\_\_\_\_
- **Length of treatment** \_\_\_\_\_
  - 60 min
  - 45 min

Prescribed by Doctor: \_\_\_\_\_

Signature of the Doctor \_\_\_\_\_

Date \_\_\_\_\_ Time \_\_\_\_\_

ALLERGY&ASTHMA LTD.

320B, Earlsfield Road  
LONDON  
SW18 3EJ

## **SPELEOTHERAPY ('Halotherapy')** Dry Sodium Chloride Aerosol Inhalation

**'SPELEOTHERAPY'**, or underground climatotherapy is a complementary respiratory treatment and has been used widely in Eastern Europe and Russia for more than half a century. It utilizes a microclimate dry saline aerosol inhalation to provide systemic relief from respiratory diseases. In addition, North American and foreign clinical trials have shown that sodium chloride can improve sinus and lung function resulting in improved mucus clearance (and unwanted inhaled particulate) and relief for sinusitis. The *dry* saline aerosol is able to penetrate deep into the respiratory tract due to the small size of the particulate and its' negative charge. The effects are manifold: mucolytic, antibacterial, anti-inflammatory and immunomodulating. The experience is also more comfortable for patients than inhaled hypertonic saline aerosol solution since one inhales air as opposed to liquid.

**'HALOTHERAPY'** is a *drug-free* therapy provided in a controlled air medium that simulates the natural salt cave microclimate. Halotherapy is performed in a special room (chamber) with walls and floor being covered with rock salt. This special salt covering acts as a buffer for air moisture and helps maintain the environmental aseptic properties. Dry sodium chloride aerosol containing particles of 1-5µm in size is produced by a special nebulizer and released into the chamber. Halotherapy provides a specified concentration of dry salt aerosol under controlled conditions of temperature and relative humidity, while regulating the size of the dry sodium aerosol particles. The halocomplex controls and maintains the concentration of highly dispersed aerosol at four pre-set levels (1, 2.2, 5.5, 16mg/m<sup>3</sup>) providing a concentration of dry sodium chloride aerosol from 1 to 16mg/m<sup>3</sup>.

Due to the aerosol's curative influence, positive symptom dynamics are evident during 'HT' in improved respiratory tract drainage function: relief of sputum expectoration, sputum viscosity reduction, relief of coughing and improved auscultation picture of the lungs.

### *MEDICAL DEVICE CLASSIFICATION:*

Through correspondence with the 'Speleotherapy' Clinic in April 2002, Health Canada determined that the Halocomplex Aerosol Chamber is a class 1 device, by Rule 7(1) and Rule 12 of the Canadian Medical Device Regulations.

## Patient Benefits

*Sodium chloride aerosol improves rheological properties of bronchial contents, decreases edema of bronchial mucosa and contributes to the functioning of cilia epithelium. It has a bactericidal action and enhances the activity of alveolar macrophages.\**

In addition, Halotherapy provides a host of benefits:

- ◆ Reduced bronchial hyperresponsiveness as an add-on therapy in asthmatics with low to moderate doses of inhaled steroids\*\*\*
- ◆ Relieved cough, improved sputum properties, improved auscultative findings and functional parameters. Inhalation of the DSCA, characterized by the fixed density and low doses of sodium chloride, rendered sanitary action in the respiratory tract and it was noted that the therapy could be used for primary prevention of COPD\*\*
- ◆ The number and intensity of asthma attacks was reduced and respiratory discomfort decreased or disappeared, which allowed in a number of cases, the reduction or elimination of prescribed beta-agonists \*
- ◆ Better drain function of patients' airways was observed along with alleviation of sputum secretion, decrease in viscosity, relief from coughs and improvement of the auscultative picture of the lungs\*
- ◆ Noteably, there was a positive influence on bronchial obstruction\*
- ◆ Improvement of mucociliary clearance and decrease of bronchial inflammation was evident\*
- ◆ Average amount of neutrophils, macrophages and lymphocytes diminished\*
- ◆ There was a decrease in the amount of neutrophils and pathogenic microorganisms and an increase of the amount of alveolar macrophages in bronchial secretion of patients with BA, chronic obstructive bronchitis and cystic fibrosis after HT (Voronina et al, 1994)\*
- ◆ Elimination of pathogenic microorganisms and a decrease in inflammatory reaction of the mucosa was observed\*
- ◆ Research confirmed the positive effects of HT on the state of humoral and cellular immunity in patients with BA (Spesiviykh et al, 1990, Torokhtin et al, 1987); decrease of IgE level was observed (Dityatkovskaya et al, 1993)\*
- ◆ Contributed bactericidal and bacteriostatic effects on the respiratory airways microflora and showed prevention of the development of inflammatory processes (Simyonka, 1989, Rein & Mandell, 1973)\*
- ◆ Low doses of DSCA had a beneficial effect on phagocytic activity of alveolar macrophages (Konovalov et al, 1992) and thus on bronchial clearance and elimination of foreign agents\*

In summary, theoretical prerequisites and the data collected during clinical studies suggest the efficacy of HT results from the combination of the curative properties of dry sodium chloride aerosol and the method of its administration.\*

\*Chervinskaya AV, Zilber NA. Halotherapy for treatment of respiratory diseases. *J Aerosol Med* 1995;8(3):221-232.

\*\* Chervinskaya AV. Respiratory hygiene with dry sodium chloride aerosol. 14th Annual Congress of the Respiratory Society, Glasgow, September 2004. Session "Clinical and physiological observations from health to chronic illness", Poster P2514

\*\*\* J. Hedman, T. Hugg, J. Sandell, T. Haahtela. The effect of salt chamber treatment on bronchial hyperresponsiveness in asthmatics. *Allergy* 2006; 61: 605-610