GUNA®-COMPLEX n.1

Clinical Studies

1) COMPARATIVE EVALUATION OF GUNA®-COMPLEX n.1 vs VACCINE FOR THE INFLUENZA SYNDROME PREVENTION IN PEDIATRICS
A prospective, multicentre, randomized, controlled study
M. Colombo, G. Rigamonti, M.L. Danza, A. Bruno
LA MEDICINA BIOLOGICA 2007/3; 3-10

2) UPPER RESPIRATORY INFECTIONS PREVENTION IN CHILDREN WITH GUNA®-COMPLEX n.1
A multicentre, controlled, randomized study
C. Supino
LA MEDICINA BIOLOGICA 2002/3; 19-23

INTERNATIONAL LITERATURE REVIEW
During the period October 2004-February 2005, 176 school children aged between 2 and 6 years old, all attending school or kindergarten, under the care of a general pediatrician in 4 pediatric clinics operating within the National Health Service (ASL 2) in Milan, Italy were randomized to receive preventive therapy with Vaxigrip® Bambini Split anti-influenza vaccine (n=45), Guna®-Complex n.1 (n=45) or both (n=10). The control group was made up of 76 children of the same age group who did not receive treatment.

The study highlighted the non-inferiority of the preventive homoeopathic therapy versus the conventional control therapy with significant protection against influenzal infections and, as regards Guna®-Complex n.1, against para-influenzal infections as well, which can be interpreted as the immuno-prophylactic activity of the homoeopathic medicine even in the case of the frequent antigenic drift that is characteristic of the influenzal virus (Fig. 1).

The data which emerged relating to the reciprocal synergistic effect shown when the vaccine and Guna®-Complex n.1 were given at the same time are of particular interest; this opens new paths for integration between Conventional and Non-Conventional Medicine. (Fig. 2).

Furthermore, both immunoprophylaxis forms showed a perceptible reduction in the days of absence from school and the parents’ absence from work as well as in the severity of the overt clinical picture in the non-responders. Guna®-Complex n.1’s tolerability was total; only one case of adverse reaction to the vaccine was reported during the course of this study.

With regard to the initial objectives of the study, the data were analyzed and elaborated according to the Odds Ratio (OR) analysis model taking into account the confidence interval (CI). This statistical analysis model allowed assessment of the non-inferiority of Guna®-Complex n.1 versus the anti-influenza vaccine since the result expresses the absolute significance of positive or negative preventive efficacy and not a percentage scale of effectiveness.

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Infections of the upper respiratory tract (URI – upper respiratory infections) represent the most frequent pathological condition during childhood, generally they do not cause serious clinical consequences, even though they affect the child’s quality of life and entail high medical-social costs.

It is well known that the pathogens involved in URIs are mainly viruses, mycoplasmas and bacteria: they are located at different levels and cause contiguous clinical conditions and the localization may be either synchronous or it may occur in succession.

The pathological process is the same at all levels: inflammation and edema of the mucous membranes, vascular congestion, hyper secretion of mucus and alterations in the structure and function of the ciliary apparatus.

The study protocol involved administration of a complex homoeopathic medicine (Guna®-Complex n.1) for 3 consecutive months at one monodose a week taken sublingually, whilst the standard version uses the administration of bacterial lysates (Biomunil®, Bronchovaxom®, Bronchomunal®) at a dosage of 4 sachets a week for the first week, then 4 sachets a month for the following three months (Biomunil®), whilst for Bronchovaxom® the dosage was 10 tablets a month for three months.

The morbidity factor (period of observation 165 days) was the considered parameter.

The study demonstrates the greater efficacy of the homoeopathic therapy; 50% morbidity was reported in the group treated with bacterial lysates, whilst there was 39% morbidity in the group treated with the homoeopathic medicine (Fig. 2).

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**GUNA®-COMPLEX n.1**

- **Guna®-Complex n.1** is a complex homeopathic medicine indicated for children, adults and elderly people for the prevention and treatment of influenzal and para-influenzal syndromes.

- An original and innovative formula is the basis of **Guna®-Complex n.1** success. The immunostimulant action of its main component (Anas barbariae hepatis et cordis extractum 7CH)\(^1\) is strengthened by the presence of 2 other remedies (Haemophilus influenza 9CH and Vincetoxicum 5CH) which, acting in mutual synergy, promote, enhance and reinforce the medicine global anti-influenzal effect.

- **Guna®-Complex n.1** guarantees excellent anti-influenzal prevention thanks to the natural defenses reinforcement against influenza and para-influenza viruses, in particular by means of an increase in the cell-mediated response of nonspecific and specific cytolysis of the cell infected by the virus [T-helper lymphocytes, cytotoxic T lymphocytes, NK (natural killer) cells], and those of a humoral nature with an increase of lysozyme, γ-interferon and the cytokine cascade. Immunoprophylaxis induced by **Guna®-Complex n.1** follows a characteristic Gaussian temporal course consisting of mainly cell-mediated immune stimulation and therefore not endowed with "memory" (Fig. 1).

- This particular type of response ensures effective coverage even in cases (increasingly frequent) where the viruses alter their conformation (antigenic drift/shift) which often renders ineffective the antibody response evoked by the vaccine.

- The presence in the medicine of 4 “symptomatic” remedies is of particular interest (Aconitum napellus 5CH, Belladonna 5CH, Cuprum 3CH, Echinacea angustifolia 3CH), which support the immunostimulant components of **Guna®-Complex n.1** to enhance its action and ensure a quick resolution of the inflammatory processes affecting the upper, middle and lower respiratory tracts, possible entry portals for the influenza infection. The excellent combination of immunostimulant and symptomatic remedies, furthermore, renders **Guna®-Complex n.1** effective right from the onset of the influenzal disorder.

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\(^1\) It has been shown that influenza viruses find a reservoir in the heart and the liver of this species of duck, which therefore becomes the healthy carrier of influenza viruses during inter-epidemic periods. The particular homoeopathic preparation causes these organs, even if they are not the pathological condition site, to be carriers of specific antigens: the virus genetic material would induce the cells to synthesize precise viral proteins (those present in all influenza viruses strains). The proteins, even if produced by the same host organism, are foreign and would be considered as a target by the immune system, which would, therefore, prepare itself for infection by cloning T cells and NK cells.
In the homeopharmacological structure of Guna®-Complex n.1 is contained the rationale of anti-influenzal immunoprophylaxis and of the influenza symptoms treatment.

Nucleus of Immunostimulation
ANAS BARBARIAE HEPATIS ET CORDIS EXTRACTUM 7CH
HAEMOPHILUS INFLUENZAE 9CH
VINCETOXICUM 5CH

Compartment of cell-mediated immunity
ANAS BARBARIAE HEPATIS ET CORDIS EXTRACTUM 7CH
HAEMOPHILUS INFLUENZAE 9CH

+ 

Cytotoxic T lymphocytes
NK Cells

Specific cytolysis of the cell infected by the influenza virus (cytotoxic T lymphocytes)
Nonspecific cytolysis of the cell infected by the influenza virus (NK cells)

Compartment of humoral immunity
VINCETOXICUM 5CH

+ 

Th1

γ-Interferon

Inhibition of viral RNA synthesis
• Aconitum napellus 5CH
• Belladonna 5CH
• Echinacea angustifolia 3CH
• Vincetoxicum 5CH
• Anas barbara hepatitis et cordis extractum 7CH
• Cuprum 3CH
• Haemophilus influenzae 9CH
• Sucrose

**Nucleus of symptomatic remedies**

**CUPRUM 3CH**
**ACONITUM NAPELLUS 5CH**
**BELLADONNA 5CH**
**ECHINACEA ANGUSTIFOLIA 3CH**

**Tropism for Nervous System and striped and plain muscles**

Influenza-induced myalgia. Anti-pyretic activity caused by heat dispersion by convection.

**Tropism for the RES**

Inflammatory process immunomodulation Antiseptic action.

**Tropism for the CNS, PNS**

Localized acute inflammations, in the initial phase. Evolution of the “Aconitum” picture.

**Tropism for CNS, PNS and Cardiovascular System.**

Remedy in the initial phases of acute febrile reaction with violent and sudden onset.
**A nas barbariae hepatis et cordis extractum**

Liver and heart Anas barbariae homogenate is particularly rich in viral DNA and RNA; in fact, during the interepidemic periods the influenza virus stays in these two organs. The homeopharmacologic activity of the homogenate is similar to that of the nosodes: Anas barbariae stimulates the cell-mediated immune response (mainly T cytotoxic and Natural Killer lymphocytes) aimed at the cellular lysis.

**H aemophilus influenzae**

The homeopathic dilution of expectorate (containing influenza viruses) of influenza affected patients is able to activate the Immune System and to induce a cell-mediated response (macrophages, T cytotoxic lymphocytes and Natural Killer cells) that is specific against the cells infected by the influenza and parainfluenza virus. The presence of Influenzinum synergizes the action of Anas barbariae.

**Vincetoxicum**

The action of Vincetoxicum is similar to that of vincetoxin, aconitin and hippuric acid and has a tropism for the vessels, the Sympathetic Nervous System and the Immune System, on which it mainly stimulates the activity of Th1 lymphocytes (Interferon gamma).

**Aconitum napellus**

It has a tropism for the CNS, the PNS and the circulatory system. Aconitum is active on the neurogenic phase of inflammation. The symptoms on which it acts are acute, strong, rapid and sudden expression of a general affection of the body. Pathognomonic sign of Aconitum is fever (above all during the onset phase) that is characterized by: congestion, redness of the face, dry skin, myosis, psychical state with anguish, restlessness and fear.

**Belladonna**

It has a tropism for the CNS and the VNS. The action of Belladonna is clearly anti-inflammatory; it acts selectively on the vascular phase of inflammation but in general on the whole inflammatory syndrome, including redness, hyperthermia, pain, vascular pulsation in particular involving the mucosa, the lymphatic and the connective tissue. It has a strong antipyretic activity.

**Echinacea angustifolia**

It has an anti-inflammatory and antiseptic action. Tropism for the reticuloendothelial system. Echinacea can slow down the septic development of the pathology and activate the restoration mechanisms of the tissues; it is considered one of the most important remedies for the septic states and for infective pathologies in general, with a tendency to chronicization and recurrences.

**Cuprum**

Main tropism for the Nervous System on which it acts by reducing the convulsive syndromes that are characterized by tonic-clonic contractions of the skeletal muscles; Cuprum is active also on the spastic forms of the plain muscles (muscular layer in the vascular walls). Cuprum is known as having antalgic activity (modulation of the response to the prostaglandin stimulus).

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**DIRECTIONS FOR USE:**

Adults, the elderly & children 2 years old and above:
Tip the entire contents of the tube into the mouth and allow to dissolve. Repeat every 6 hours, up to 3 time a day until symptoms are relieved.

Children under 2 years old:
As recommended by your doctor. Consult a doctor if symptoms worsen or persist.

**PACKAGING**

Pack of 6 tubes.
Each tube contains 1 g of pills.