



**The treatment of children with recurrent infections of  
the respiratory tract  
by the sublingual administration of  
UTILIN - „S“ injection solution**

**by**

**Wang Yunfang**

**Li Ming**

**Dong Wei**

**Wang Xiaoming**

**Sichuan Provincial People's Hospital,  
Dept. of Paediatrics**

## Introduction

In paediatric medicine, recurrent infections of the airway are a well-known problem particularly in pre-school age children, and their treatment is often very difficult because of the particular physiological conditions and the lack of compliance. Different therapies are used with varying degrees of success. One noteworthy form of therapy of recurrent respiratory infections was developed by the Department of Paediatrics of the Sichuan Provincial People's Hospital in China using UTILIN „S“, which is imported into China by the Chengdu Jinxing Sanum Pharmaceutical Corp., a joint venture company with SANUM-Kehlbeck GmbH & Co KG. The detailed description follows.

## Data and methods

### I. Clinical data

The children were tested according to the standards<sup>1</sup> of the „Chengdu Respiration Convention of 1987“. The children in the group treated (19 boys and 17 girls) were between three and six years old, whilst the children in the control group (17 girls and 18 boys) were between three and 5½ years old. The control group matched the treated group in sex, age and frequency of illness (Table 1).

### II. Methods

1. One ampoule of the UTILIN „S“ injection solution which had been

		TREATMENT GROUP	CONTROL GROUP
SEX	Boys	19	18
	Girls	17	17
Age		4.5 ± 1.4	4.1 ± 1.2
FREQUENCY OF ILLNESS PER YEAR	Twice	17	15
	Once	14	16
	Once every two months	5	4

Table 1: Distributions in the two test groups before the start of treatment

packaged by the Chengdu Jinxing Sanum Pharmaceutical Corp. was given sublingually once a week over a period of eight weeks. On the first occasion the form of administration of the UTILIN „S“ was very weak in terms of acid resistance, the second time the UTILIN „S“ was weakly acid resistant, and for the other six administrations the UTILIN „S“ was medium weak in terms of acid resistance. The follow-up period after the final administration lasted three months. The children in the control group were given conventional treatment if a clinically manifest infection occurred.

2. *Methods of investigation:* Venous blood was taken from all the children in the study before and after the UTILIN „S“ injection solution was administered in order to test its influence on the IgG,

IgA, IgM and sub-populations of T-lymphocytes.

### III. Assessment of the results of treatment

Appropriate staff were detailed to take notes. The categories for the assessment of the results of treatment were as follows:

- *good results of treatment* (no further infection occurred within three months after the eight-week course of treatment)
- *fair results of treatment* (the length of infections was greatly reduced; nevertheless there were one or two short periods of illness after the final dose of the remedy)
- *ineffective* (no change in frequency and course of illnesses).

#### IV. Statistical methods

The statistical significance of the results of the investigation was analysed using the  $\chi^2$  and t-tests.

### Results

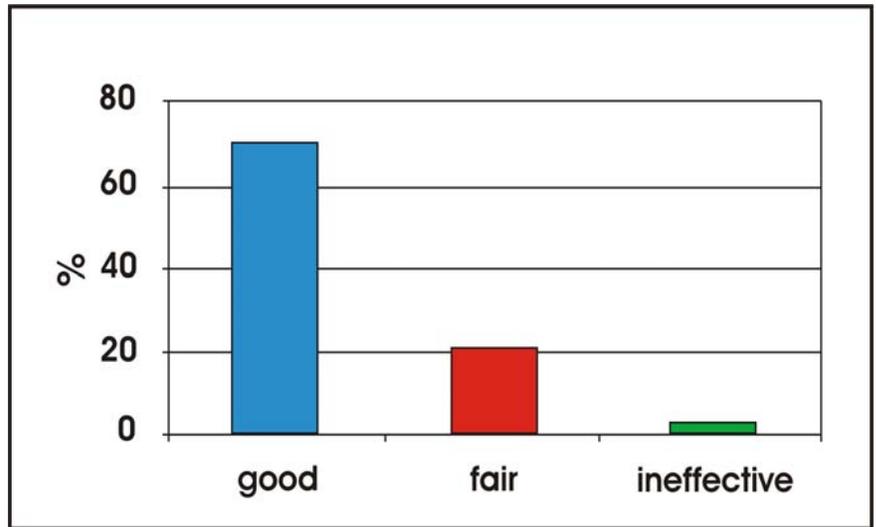
#### I. Comparison of the curative effect between the treated group and the control group

The treatment results achieved were „good“ in 26 children (72 %), „fair“ in eight children (22 %) (Graph 1). Only two children (6 %) did not react to the treatment.

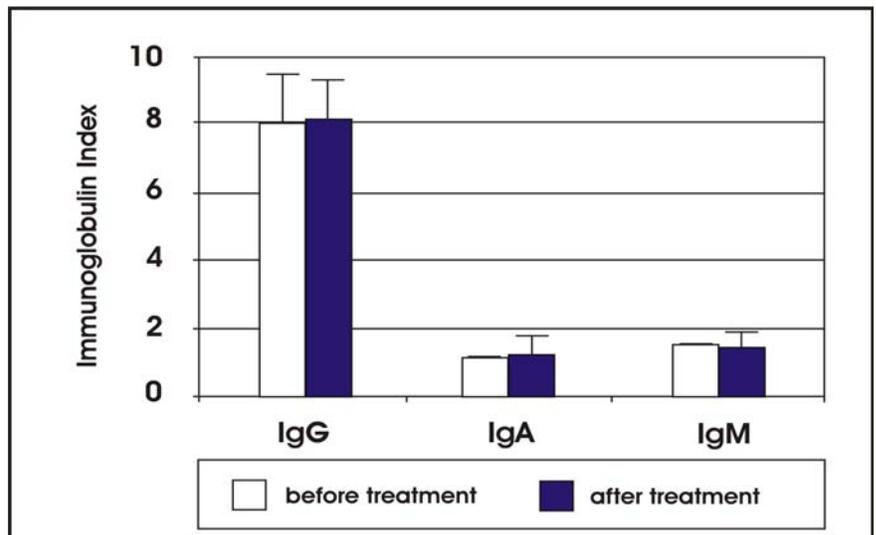
In the control group 30 children presented multiple recurrent respiratory infections during the period of investigation; only in five children did such infections occur only once. These differences in frequency were statistically highly significant.

#### II. Comparison of the immunoglobulin content

Measured against normal values of 7.23 to 16.85 g/l for IgG, 0.69 to 3.82 g/l for IgA and 0.63 to 2.77 g/l for IgM, before the treatment 10 out of 36 children showed low values for IgG and six children low values for IgA (Graph 2). Only in one case did the values still remain below the norm after treatment, although they had risen marginally. The changes in these parameters were not significant statistically.



Graph 1: Representation of the clinical results of treatment



Graph 2: Immunoglobulin index before and after treatment

#### III. Comparison of the T-lymphocyte populations

The numbers of CD3, CD4 and CD8 cells all rose by a statistically significant amount (Graph 3).

#### IV. Side effects

No undesirable effects of the remedies were observed

during the investigations.

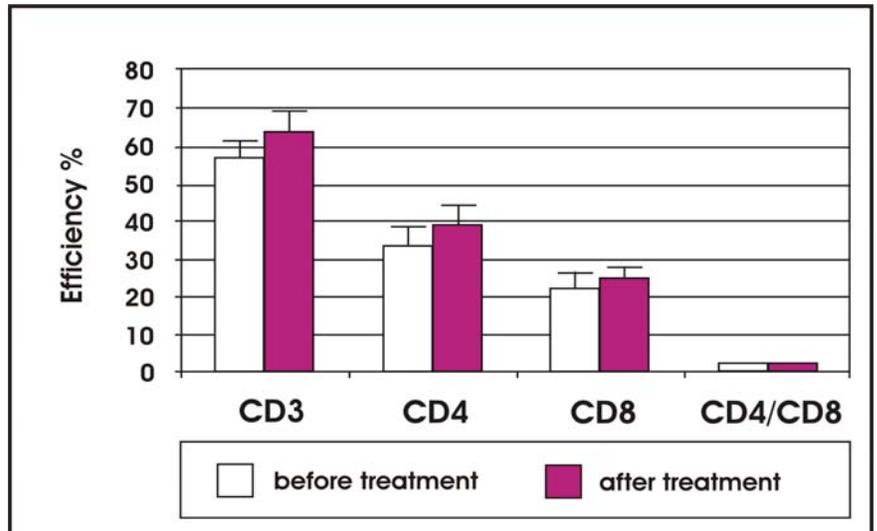
### Discussion

The pathomechanism of recurrent respiratory infections in children is relatively complicated and influenced by many factors. A few researchers<sup>2,3</sup> are of the opinion that a weakened immune system is significant in such cases, particularly at cell level. A drop in the number

of T-lymphocytes and helper cells signifies a reduction in the ability to form IL-2 and IL-4, and a decrease in the production of anti-bodies results in less defence against infections. In the study reduced CD4 values were found before treatment, however there were no differences as regards CD3 and CD8. This could however be caused by the relatively small number of cases.

At present the use of immunologically active remedies is an important method in the treatment of recurrent respiratory infections. A few such substances have proved their worth in clinical application. In this study particularly good results of treatment were achieved by administering the remedy under the tongue. Considerably better results were achieved by this method of application than in the control group. As a result of treatment the values for IgG and IgA rose in the same way as those for CD3, CD4 and CD8.

The active substance in UTILIN, „S“ is *Mycobacterium phlei*. The remedy has specific and unspecific characteristics which modulate the immune system. In this way it activates T-lymphocytes and T-helper cells. The remedy is also indirectly able to increase the production of antibodies and thus strengthen the immune defence.



Graph 3: Comparison of the T lymphocyte populations before and after treatment.

Intramuscular injections in very high dosages can in rare cases lead to local reactions. For this reason and also because of better compliance, sublingual administration has proved its value particularly in the treatment of children. In this area of the mouth there are many blood and lymph vessels, so that fast resorption of the active substance is guaranteed. This also avoids the breakdown of the active substance by the liver.

Sub-unit in Patients with Iterative Infection along Respiratory Tract. Journals of Xi'an Medical University 13 (1), 50.

<sup>4</sup>Zhang Qikai (1990): Basic Principium of Medicine Design. China Medicine Technology Press, 47.

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<sup>1</sup> Zhang Zhijing, Sheng Jingyun, Wang Yunfang et al. (1988): Diagnosis Standard on Infection-apt Children. China Paediatrics Magazine 26 (1), 41.

<sup>2</sup> Dai Zhongdong, Lu Jing, Zhang Zhijing (1993): A Study on the Treatment of Repeated Respiratory Infection by Thymus. China Paediatrics Magazine 31 (6), 35.

<sup>3</sup> Li Yuehua, Di Zuoting (1992): T Cells