

## **Double blind, randomized placebo controlled mono centre clinical study on the influence of Rescue® Bach flower remedy on erythrocyte rouleaux formation**

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**Abstract:** The current study investigated the effect of Bach flower Rescue®-drops on erythrocyte rouleaux formation. Bach flower Rescue®-drops were used, because they are said to be useful in situations of emergency stress. Erythrocyte rouleaux formation was monitored as the main parameter because it is physiologically linked to vasodilatation, which is a counteraction to stress. A double-blind, randomized, placebo controlled mono centre clinical study was performed including 32 healthy test persons in a relaxed state. Volunteers in group 1 received Rescue®-drops, whereas test persons in group 2 obtained a placebo solution. Blood samples were analyzed under a dark field microscope before and after intake. Statistical analysis showed a highly significant difference between group 1 and 2 ( $p=0.000$ ), which leads to the conclusion that Rescue®-drops cause vasodilatation with a following erythrocyte rouleaux formation.

**Keywords:** Integrative medicine, holistic health, stress, Rescue® Bach flower remedy, vasodilatation, erythrocyte rouleaux formation

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### **INTRODUCTION**

The concept of “stress“ was first documented by Selye in 1936 (1). In the course of his investigations it was found to be a major causative factor for the development of psychosomatic diseases. The economic costs of stress are manifold. Data from the European Union have shown that the overall costs associated with mental health problems due to stress have been estimated to be in the range of about 265 billion Euros creating an enormous economical damage(2).

Different treatments are currently available in order to manage stress and its symptoms. Psychotherapy offers different strategies, such as the time-, stimulus-, excitement- and harassment-management. Relaxation methods, such as autogenic training, yoga, Jacobsen’s progressive muscle relaxation technique, and other treatments for stress equalization and adaptation are available.

An incredibly high amount of money (only in Germany about €9 billion) spent on anxiety related drugs, gives a clear insight into patient’s preferred treatment of stress coping.

The Bach flower therapy (3,4) is basically a form of plant therapy. It is applied to influence somatic and psychogenic phenomena. The so called Rescue®-drops, to name one of the applications, has been recommended especially in situations of emergency. These Bach flower Rescue®-drops are a combination of: Clematis, Impatiens, Rock Rose and Star of Bethlehem.

We decided to use this blend in the study presented here to determine a reaction, especially because no medical concerns regarding its application were expected. Vasoconstriction, the physiological reaction of the human body under acute stress, is controlled by the sympathetic nervous system. Counteraction is induced by the endothelial nitrogen monoxidase (eNOS) causing vasodilatation (5). Different vessel diameters are generated by specific intravascular pressure ratios. So called "rouleaux" formation, the physiologically erythrocyte agglomeration, is caused in dilated vessels and disrupted under vasoconstriction due to a pressure increase (6,7). Based on this knowledge, we assessed the erythrocyte rouleaux formation, in stress, as a parameter worthwhile of being investigated (8).

Our study focused on the question if Bach flower Rescue®-drops composition may cause erythrocyte rouleaux formation in a healthy test population. The main goal was to investigate the effect of Rescue®-drops on the physiology of stress.

## **METHODS**

In the following work we performed a double-blind, randomized, placebo controlled mono-centric clinical study. Forty nine healthy volunteers, 29 women and 20 men, at ages ranging from 18 to 75 years were included in this study. Persons under anti-coagulation, anti-hypertensive and anti-hypotensive drug therapy, as well as alcohol addicts were excluded from participating. None of the participants was under special stress during the study period.

We used dark field microscopy, a special type of light microscopy. It visualizes transparent and low-contrast objects without staining, which demonstrated an ideal means to analyze the unaltered blood flow. The fact that no staining is required makes an observation of cellular components of the blood very simple.

For the examination we used a laboratory microscope (Modell Novel N-400, Hengtech Optical Instruments, Viernheim, Germany) with a dark field condensor N. A. 1,25 (oil) (Hengtech Optical Instruments, Viernheim, Germany) at 100x magnification. Archival storage and documentation was performed using a digital camera for microscopes (HDCE, Hengtech Optical Instruments, Viernheim, Germany) and special software (Software Novel INOVO®-USB.2.0-Cam, Hengtech Optical Instruments, Viernheim, Germany).

Blood samples were taken from the finger pad of healthy test persons and analyzed under the dark field microscope regarding the presence and length of rouleaux. Seventeen volunteers had to be excluded from further attendance due to a significant initial rouleaux formation.

From the remaining 32 test persons 16 volunteers received, randomly, solution number 1, containing the Bach flower Rescue®-drops as are commercially available (containing 27% grape alcohol). The second test population obtained solution number 2, a placebo solution (pure 27% grape alcohol). Solutions (4 drops) were administered orally for one time. Subsequently, a second examination regarding erythrocyte rouleaux formation was performed with the goal to determine differences before and after the treatment. Basic and second exploration was digitally photographed and archived.

### **Statistical analysis**

For statistical analysis, we chose an analysis of variance for repeated measures with time as factor 2. It turned out to be an ideal approach to investigate the effects on the two experimental groups in relation to the time.

### **RESULTS**

Table 1 shows a significant relation between the group and the point in time of measurement (“factor one”). At time point 1 no difference between the groups was determined, which led to the decision to ignore the presence of main effect for group 1 (significant difference between the groups over a certain time frame) and factor 1 (significant difference between the time points within the groups). F evaluates the effect of the groups.

Table 1.

Table 2 shows a highly significant ( $F(1/30) = 119.339$ ,  $p = 0.000$ ) change between different time points in group 1 only, but not in group 2.

Table 2.

Each F determines the multivariate simple effects of factor 1 within each combination of level of other shown effects. Statistical analysis showed a highly significant change of group 1 = verum group after Rescue®-drop intake. A significance in group 2 = placebo group was not found. In all 16 test persons receiving the Rescue®-drops (verum group), an increasing erythrocyte rouleaux formation (figure 1) was found

Figure 1

**Figure 1. Degree of rouleaux formation in verum group. See text for explanation**

Figure 2

**Figure 2. Degree of rouleaux formation in placebo group. See text for explanation**

One case the control group showed an increase in erythrocyte rouleaux formation. A single test person featuring slightly increased erythrocyte rouleaux formation on primary checkup was free from further changes after the intake of placebo solution.

### **DISCUSSION**

Aim of this study was to determine the possibility of effect detection after the application of Rescue®-drops using a physiological indicator. Therefore, the model of a placebo-controlled, double-blind study was used. Erythrocyte rouleaux formation as a sign of counter reaction to stress was investigated in a

healthy test population. A highly significant effect of Rescue®-drops was determined. Effect was identified by presence of rouleaux formation using a dark field microscope. This physiological reaction was interpreted as a sign of capillary vasodilatation and secondarily as stress regulation.

According to previous studies, the above documented physiological effect may not be strong enough to cause a subjectively detectable improvement when compared to the placebo group. It is recommended to repeat the present study involving an independent laboratory.

Further investigations will be necessary using a larger test population. The combination of clinical and psychological interventions would be a useful approach in this regard, and quality of life assessment may be an important tool.

### **CONCLUSION**

Rescue®-drops caused erythrocyte rouleaux formation. It can be assumed, that this is caused by vasodilatation in terms of stress management.

### **CONFLICT OF INTEREST**

None. There is no commercial connection between the authors and Bach flower pharmaceutical industry.

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