

**Seating System for Scoliosis in Non-ambulatory Children with Cerebral Palsy:**  
**A Randomized Controlled Trial**

Clinical trials number: NCT03862625

Date of Data: 01.04.2016

**STUDY PROTOCOL AND INFORMED CONSENT FORM**

Scoliosis is the deviation in the normal vertical spine. A 3-dimensional structural deformity develops in the spine. Scoliosis; depending on whether the deformity is fixed or not, it can be classified as structural and non-structural scoliosis. Structural scoliosis is a scoliosis that does not change the deformity and is accompanied by anatomical changes. In non-structural scoliosis, the curvature can be improved by changing the patient's body posture.

Neuromuscular scoliosis is classified as a subgroup in structural scoliosis. It is a muscle imbalance due to diseases at the brain, medulla spinalis, peripheral nerves, musculoskeletal junction or muscle level. In neuromuscular scoliosis, the curvature of the spine is progressive and may continue to progress even if the patient's skeletal development is completed. Curvatures, which are softer in the beginning, quickly turn hard and uncorrectable if the treatment is delayed, making the treatment very difficult.

Although conservative and surgical treatment methods are used in neuromuscular scoliosis, there is no consensus on the treatment algorithm. Recently, although it has become prominent that surgery is effective in the early period, patients tend to use more conservative methods because of the serious side effects or the unsuitability of some patients for anesthesia or surgery depending on the extent of scoliosis.

Conservative treatments include orthosis, seating devices, and scoliosis-specific exercises. The aim of treatment is to prevent the progression of the curvature as well as to increase the patient's functions. For this reason, it is important to have a spine and pelvis that will ensure a balanced sitting. Orthosis is very limited effects in neuromuscular scoliosis. There is no evidence that orthosis treatment prevents deformity due to neuromuscular scoliosis. The soft orthoses are used for these patients. Studies have shown that soft orthoses improve the sitting balance in the short term and can help maintain the functional level of the patients. Despite the possibility of stopping the progression, there are few evidence of regression of the curvature.

In exercises, the aim is to correct the muscle imbalance that causes scoliosis and to stabilize the spine. It has been reported that regular stretching exercises may be beneficial in neuromuscular scoliosis, but this treatment will not prevent the progression of the curvature.

The aim of the custom molded seating systems is providing a balanced fit to the patient's spine by providing support from the appropriate areas, and thus prevent the progress of the curvature by fixing the body. In addition, it has been found to help the patient's sitting balance. However, there

are not many studies evaluating the effectiveness of sitting pattern in the neuromuscular scoliosis group. In the literature, there is no study comparing the effectiveness of the seating systems with exercise therapy and showing its superiority over each other.

Using the seating systems and exercise therapy has no serious side effects. Possible side effects are pressure ulcers due to a long stay in the seating system, soft tissue injuries due to over-tightening material, deformities in the musculoskeletal system as a result of exertion. Since patients with a curvature of more than 40 degrees and who are thought to benefit more from surgical treatment were not included in the study, there would be no significant delay in the treatment of these patients. Pressure ulcers may exist in areas such as hips and waist that come into contact with the seating surface will be especially evaluated in each patient and patients with pressure ulcers will not be included in the study. In addition, exercise training will be given by an experienced trainer with appropriate techniques, so deformities due to exercise will be prevented.

Thirty patients with neuromuscular scoliosis and cerebral palsy will be included in the study. The patients will be divided into two groups according to the order of admission to the department using computer-generated random numbers: Seating system with exercise group (Group 1, n=15) and Exercise group (Group 2, n=15). Scoliosis specific exercises will be taught to both groups. The first sessions will be applied with the patient and the patient's parents will be trained on exercises. After that, the patients will be called every week until the first month and it will be checked whether their exercises are applied correctly. In the first group, patients will use a seating system. This system will be specially prepared for each patient and these patients will be asked to spend at least 4 hours a day in the system.

Evaluations will be made at the beginning and in 1 and 3 months. Evaluation and treatment of patients will be made by Dr. Merve Damla Korkmaz. With the findings to be obtained, the effect of seating system treatment on the progression of the curvature in neuromuscular scoliosis and the level of hip dislocation will be determined.

In this research, you will enable us to evaluate the effectiveness of the seating system on the progression of curvature, the level of hip dislocation, functional activities, arm and leg functions, sitting balance, movement mechanism, and you will contribute to obtaining scientific data.

#### **INFORMATION ABOUT THE RIGHTS OF VOLUNTEERS**

Volunteers have the right to refuse to participate in this research. Volunteers may withdraw from the study by notifying the researcher at any time or they may be excluded from the study when deemed necessary by the researcher. The treatments of the volunteers excluded from the study, which are deemed appropriate for their current situation, will be continued with the applied or a different treatment.

In the event that the volunteer does not accept the study or is removed from the study program for any reason, there will be no disruption in the treatment of his disease.

Volunteers will not be liable for any monetary responsibility for research expenses. In addition, no payment will be made to the volunteer or his family.

The identity information of the volunteers and their families will be kept confidential.

### **Participant's / Patient's Statement**

Dear Prof. Dr. A. Resa Aydin and Dr. Merve Damla Korkmaz stated that a medical research will be carried out in the Department of Physical Medicine and Rehabilitation of Istanbul Faculty of Medicine and the above information about this research was transferred to me. After this information I was invited as a "participant" (subject) to such a study.

If I participate in this research, I believe that the confidentiality of my information, which should remain between me and the physician, will be approached with great care and respect during this research. During the use of research results for educational and scientific purposes, my personal information should be carefully

I have been given sufficient confidence that it will be protected.

During the execution of the project, I can withdraw from the research without giving any reason. (However, in order not to leave the researchers in a difficult situation, I do not want to inform me in advance that I will withdraw

I can also be excluded from the research by the researcher, provided that my medical condition is not harmed.

I do not take any financial responsibility for the expenses for research.

No payment will be made to me either. Either directly or indirectly, due to reasons arising from research practice.

I have been assured that any medical intervention will be provided in the event of any health problem that may arise due to direct or indirect reasons arising from the research practice. (I will not be under a financial burden regarding these medical interventions.)

When I encounter a health problem during the research, I can call Prof. Dr. A. Resa Aydin and Dr. Merve Damla Korkmaz from the phone number (05556297264 and 414 20 00-31737 / 31732) at any hour and reach at Istanbul Medical Faculty Physical Medicine and Rehabilitation Department Şehremini / Fatih / İstanbul.

I do not have to and may not participate in this research. I have not encountered any compelling behavior in my participation in the research. I also know that if I refuse to participate, it will not harm my medical care and my relationship with the doctor.

I understand all the explanations given to me in detail. I made the decision to take part in this research project as a "participant" (subject) after a certain period of reflection on my own. I accept the invitation on this subject with great satisfaction and willingness. A copy of this signed form sheet will be given to me.

### **VOLUNTEER APPROVAL FORM**

I read the text above that shows the information that should be given to the volunteer before the research. Written and verbal explanations were given to me about these. Under these circumstances,

I agree to participate, of my own free will, without any pressure or coercion.

***Participant***

Name and surname:

Address:

Phone.

Signature

***The researcher who made the statements***

Name, surname, title:

Address:

Phone.

Signature

***The organization officer who witnessed the consent process from beginning to end***

Name and surname:

Address:

Phone.

Signature