

# FamiCord Group Expanded Access Protocol Cord Blood for Brain Development

## Information for the Parent



### CORD BLOOD FOR BRAIN DEVELOPMENT

FAMICORD GROUP EXPANDED ACCESS PROTOCOL



Polski Bank  
Komórek Macierzystych  
FamiCord Group



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# FamiCord Group Expanded Access Protocol Cord Blood for Brain Development

## Information for the Parent

Thank you for your interest in **FamiCord Group Expanded Access Protocol Cord Blood For Brain Development** which researches the use of autological umbilical cord blood stem cells by the University Children Hospital in Lublin. The below brochure provides more information about our programme:

1. About the Programme
2. Documents
3. Medical test results



Polski Bank  
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FamiCord Group

## About the programme

In FamiCord Group we seek methods of use of the autological haematopoietic umbilical cord blood stem cells in order to help our patients. In light of the newest clinical research, the use of autological umbilical cord blood stem cells is highly beneficial for children suffering from cerebral palsy or autism. Early clinical trials proved that infusion of the umbilical cord blood of the child or its matching siblings (also step-siblings) is safe.<sup>1</sup>

The aim of our programme is to improve health of children suffering from cerebral palsy or autism who have their own umbilical cord blood stored in the companies of FamiCord Group.

## Medical Team Expanded Access Protocol Cord Blood for Brain Development



**Dr hab. n. med. Magdalena Chrościńska - Krawczyk, MD, PhD**, a children's neurologist, who works with the University Children's Hospital in Lublin and ŻagielMed in Lublin. Dr Chroscinska Krawczyk is a pioneer in the use of umbilical cord stem cells for an unrelated donor. In 2017, she was awarded the title of "Doctor of the Year" by Polska "The Times" Magazine. Author of many publications in the field of pediatric neurology, member of the Polish Society of Pediatric Neurology, Chairwoman of the Organizing Committee of the European Academy of Childhood Disability.



**Dr n. med. Dariusz Boruczkowski, MD**, hematologist, transplantologist, specialist in children's diseases. Medical Director of the FamiCord Group. Doctor Boruczkowski has almost 30 years of experience in treating children with stem cells - he acquired his skills at the Medical University of Karol Marcinkowski in Poznań, then he joined his medical career with the FamiCord Group. Doctor Boruczkowski watches over the quality of medical procedures and for new medical centers using stem cells in Poland and Europe.

## Is Your Child a Candidate for the Programme?

**Before you schedule an appointment, your child has to undergo screening tests which will determine if they are ready for the infusion of the autological umbilical cord blood. Once we have your written consent, we will examine the results of the umbilical cord blood and the medical documentation of the child.**

If after verification of the above information your child is qualified for the umbilical cord blood infusion, the child's umbilical cord blood is sent to the University Children Hospital in Lublin and the first umbilical cord blood infusion is scheduled.

## Visit Information

### **Before the visit**

Before your child's visit we have to check if the umbilical cord blood unit meets the infusion criteria. When the final results of the trial conducted in the umbilical cord blood sample are positive, we ask that the umbilical cord blood unit is sent to the University Children Hospital in Lublin and we schedule an appointment. The transport of the umbilical cord blood is organized in cooperation with the umbilical cord blood bank where the given blood unit is stored.

Before your visit we provide documents for you to sign. You are expected to accept and sign them in order to join the Programme. If any questions regarding declarations arise, please contact us on dedicated e-mail address and phone number before you arrive. Only if you send signed declarations back, we can schedule the date of the visit.

### **During the visit**

We kindly ask you to arrive in Lublin one day before the first infusion of the stem cells to the child and to remain in the place of accommodation at least one day after the infusion.

## **The day of the infusion**

On the day of transfusion, your child will be registered at the department of children neurology of the University Children Hospital in Lublin. Children with neurological diseases are treated in this ward. After the registration, the Child will be equipped with a catheter. Haematopoietic cord blood stem cells will be defrosted in the Bank of Haemaopoietic Progenitor Cells of the University Children Hospital.

Umbilical cord blood will be infused through the catheter within five to ten minutes. During the whole infusion, child's heart rate and the oxygen level in blood will be monitored. After the infusion, the child will remain for observation and a drip.

After the infusion, the catheter is removed and you can come back to the ward. You will be asked to call our team the day after the infusion to check in and make sure you do not have any concerns regarding your child. If everything has gone as planned, then you will be ready to travel home.

## **After the visit**

We encourage you to remain in touch with us and inform us about the progress and potential health problems of the child. Our team will also contact you half a year and a year after the cord blood infusion in order to fill out the questionnaire about the changes your child experienced after the infusion.

The number of umbilical cord blood stem cells is enough for one or two infusions for most children. During the visit, our team will discuss with you the possibility of potential further use of other cells.

## **What are the costs of the treatment?**

After the sample is qualified, the costs of the treatment will be presented by the stem cells bank storing your Child's sample.

## What potential risks and benefits arise from participation in FamiCord Group Expanded Access Protocol Cord Blood for Brain Development?

We have performed over ten umbilical cord blood infusions in the University Children Hospital in order to help children suffering from cerebral palsy and autism. According to our experience, around 1.5% of the patients experience allergic reaction during the infusion. The reaction is probably provoked by the preservative (DMSO) used during the freezing of the cells. All the allergic reactions so far have been stopped by the use of additional medicaments. Another potential risk related to the infusion which occurs even less frequently than allergic reaction might be infection or hemolytic reaction – which is the dissolution of red blood cells. Also, development of autoimmune disorder, or extremely rarely, graft versus host disease. Graft versus host disease results from reaction of the cord blood's cells against your child's body. Although we know about the possibility of the above symptoms and we will control if they occur, we have not observed them so far in any of the children we treated.

All the potential risks are listed in detail in the consent declaration. Our team will explain them thoroughly before and during the appointment.

Potential benefit of the participation in the experiment is improvement of the child's health condition through application of the umbilical cord blood stem cells from child's own umbilical cord blood. However, we cannot guarantee the benefits of the infusion of autological cord blood.

### Contact details:

If you have any questions regarding FamiCord Group Expanded Access Protocol Cord Blood for Brain Development, please do not hesitate to contact us.

You can write an e-mail to: [braindevelopment@pbkm.pl](mailto:braindevelopment@pbkm.pl),  
or call us at: +48 22 436 40 50.



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# About the Programme



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# Documents





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# Medical tests results