Clinical study Informed consent form

Project name: Longitudinal study of the quality of life and its influencing factors in children after hematopoietic stem cell transplantation

Sponsor: Sun Yat-sen Memorial Hospital of Sun Yat-sen University

Version number: Version 4.0

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project leader:

Informed consent form Informed notification page

honorific_____Children's parents:

Your child will undergo hematopoietic stem cell transplantation, and we invite you and your child to volunteer to participate in a longitudinal study of the quality of life and its influencing factors after hematopoietic SCT transplant. The aim is to evaluate the quality of life of the children after HSCT.

I. Research background

[1] Haematopoietic stem cell transplantation (hematopoietic stem cell transplantation, HSCT) is an effective treatment for a variety of hematological tumor diseases, immunodeficiency diseases and genetic metabolic diseases. This technology can rebuild the hematopoietic system and immune system of patients receiving myeloablative chemotherapy for long-term survival. Hematopoietic stem cell transplantation can be divided into three categories according to the source of stem cells: from the patient itself called autologous hematopoietic stem cell transplantation, from monozygotic twin sibling donors called syngeneic hematopoietic stem cell transplantation, from other non-identical twin donors called allogeneic hematopoietic stem cell transplantation. Hematopoietic stem cell transplantation is the only possible cure for some blood tumor diseases, immune deficiency diseases and genetic metabolic diseases.

In recent years, the cause of hematopoietic stem cell transplantation in China has developed rapidly. According to the data of China Hematopoietic Stem Cell Transplantation Registration Center, [2], in 2015, there were 104 transplant registration units nationwide, with about 5,000 hematopoietic stem cell transplantation cases. By 2021, there were a total of 174 registered units nationwide, with a total of 18110 hematopoietic stem cell transplants, including 12744 allogeneic hematopoietic stem cell transplantation and 5354 autologous hematopoietic stem cell transplantation. Among the age distribution of transplant patients, 4539 were 0 to 18 years old, accounting for 25.06% of the total.

The top three diseases among the cases of pediatric hematopoietic stem cell transplantation in Guangdong province were: severe β -thalassemia, leukemia, and aplastic anemia. With the progress of transplantation therapy and care support technology, the survival rate of hematopoietic stem cell transplantation has increased year by year, and the overall survival rate of children with some diseases such as thalassemia after hematopoietic stem cell transplantation can exceed 95% [3].

Although the overall survival rate after HSCT is good, it is still a high-risk treatment method because of the high intensity of HSCT treatment and many complications. Intensive pre-transplant therapy, such as systemic radiotherapy, myeloablative pretreatment regimen, post-transplant complications, and late effects, may affect the quality of life of the children. With the improvement of survival rate, the quality of life of children after transplantation has received more and more attention. Improving the quality of life of the children after transplantation is the ultimate goal of transplant treatment.

The quality of life of children after HSCT changes with time, and the trend is mostly to first fall and then rise. Overall, the quality of life was significantly reduced within 1 year after transplantation, and gradually recovered at 1 year after transplantation, and exceeded that before transplantation, close to the quality of life of the peer healthy population. Therefore, it is important to vertically study the quality of life of children within 1 year after transplantation and analyze the influencing factors, so as to provide a basis for formulating scientific and effective quality of life management methods and formulating targeted continuous care programs

meaning.

II. Research purpose

1. itudinal ally of the dynamic trajectory of survival at different time points after transplantation

2. Analyze the factors affecting the quality of survival at each time point

3 Looking for interventable independent risk factors of quality of survival

3. Introduction of the clinical research project

To investigate the trajectory of quality of life in children after HSCT

4. Process of the clinical study:

1, and signed the informed consent form

2. Screscreening for clinical studies

3. If you meet the inclusion conditions, you will receive a regular QOL survey

4. There were 6 time points investigated, namely, 1 week before pretreatment (T 0), the day of stem cell infusion (T 1), and transplantation

After 1 month (T 2), 3 months (T 3), 6 months (T 4), 1 year (T 5), the investigation and follow-up included the child's general condition, quality of survival score, symptom score and condition related content.

5. During the study period, you also have some corresponding responsibilities, such as visiting the hospital on time, receiving the examination, and answering the follow-up phone calls in time. At the same time, you also have the responsibility to truthfully report any physical and mental changes to you.

5. The possible benefit of the case

The study of the change trajectory of the survival quality of children after hematopoietic stem cell transplantation is conducive to find out the risk factors of the quality of life and provide a basis for taking corresponding measures to improve the quality of life.

VI. Expenses related to this study

No cost is required for this study.

7. Possible risks

This study is an investigative study that does not involve any additional research interventions and theoretically carries no risk.

VIII. Confidentiality measures

The results of this clinical study are only used for scientific purposes, so your personal data in your study and study are confidential and will be protected in accordance with the law. Your name and identity will not be disclosed and your name will not appear in any study report or public publication. The hospital ethics committee and researchers, if required by work, shall have the right to contact all your research data, including clinical observation form, experimental data, etc.

Nine, rights

This clinical study has been reviewed and approved by the Medical Ethics Committee of Sun Yat-sen Memorial Hospital, Sun Yat-sen University, and the protocol design meets the ethical requirements, which will guarantee that your interests are not infringed in this study.

Your participation in this clinical study is entirely voluntary, you may refuse to participate or withdraw at any time without discrimination or retaliation, and your medical treatment and interests will not be affected.

Ten, detailed contact information

If you have any concerns or questions about your participation in this study, you should contact:

If you have any complaints or concerns or questions about the way the study as a study subject, you

The Medical Ethics Committee of the Center can be contacted with:

Informed consent form, consent signature page

1. I have read the informed consent form carefully, and the researchers have given me detailed explanations and answered my relevant questions,

I am fully aware of the following:

(1) As the legal representative of the minor subject, I will comply with the subject information requirements and voluntarily participate in and study the study

Work fully together to truthfully and objectively provide the researchers with their health status and relevant information before participating in the study.

(2) The results of this clinical study are only used for scientific research purposes, except for the ethics committee, researchers, etc., and I participate in the study and research

Personal data is kept confidential and will be protected in accordance with the law.

(3) My participation in this clinical study is completely voluntary, and I may refuse to participate or withdraw from the study at any time without being met with

Discrimination or retaliation, and my medical treatment and rights and interests will not be affected.

Also, I declare that:

(1) During the study period, I am willing to cooperate with the nurses to receive timely follow-up visits, and truthfully report the true situation;

(2) This informed consent form has been received.

Subject legal representative signature: relationship with subject: Contact information:

Date: year month day time minutes

Witness Signature (if necessary): Contact Information:

Date: year month day time minutes

The researcher's statement

2. I have fully explained and explained to the subject the purpose of the clinical study, the study methods, operating procedures, and the possible risks and potential benefits of the subject's participation in the study, and answered all relevant questions of the subject satisfactorily.

Investigator (subject subject) signature: Contact:

Date: year month day time minutes

Informed consent form Informed notification page

Honey_____children:

You will undergo hematopoietic stem cell transplantation, and your nurse sister invites you to volunteer to participate in "a longitudinal study of the quality of life and its influencing factors after hematopoietic stem cell transplantation."The goal is to know what you do after the transplant.

1. Understand your process:

1. Get your consent

2. If you meet the requirements, the nurse sister will often contact you to ask about your situation

3. Ask you about the situation for 6 times. Before you enter the warehouse, on the day of stem cell infusion, 1 month after transplantation, 3 months after transplantation, and after transplantation

Six months, a year after the transplant, when it's time the nurse sister will contact your parents and you and ask you if you are sick,

Such as pain, no strength, poor sleep, not eating, itchy skin and so on.

For example, is it painful? How painful is it?

Do you have nausea, vomiting?

Like being tired?

4, the nurse sister needs your cooperation, for example, when the nurse sister asks you questions, I hope you can tell your true feelings.

2. Nurse sister asked your questions, generally will not cause a bad impact on you.

3. Measures of confidentiality

You answer the nurse sister's words, the nurse sister will keep it secret for you, this is a little secret between us, other else will not know Tao, so you don't have to worry about being known.

4. right

Nurse sister asked your question, if you are not willing to answer, you can not answer, nurse sister is still the same so like you.

5. Detailed contact information

If you don't understand or have any questions when she asked you later, you can call us. Her phone number is

If you have any questions about the nurse sister, if you feel unhappy and make you angry, you can call the aunts in the hospital that their phone number is

Informed consent form, consent signature page

1. I have read the informed consent form carefully, and the nurse sister has made a detailed explanation to me and answered me

Question of, I already know the following content very well:

(1) As a minor child, I volunteered to truly answer the questions raised by the nurse sister every time,

(2) I answer the nurse sister's questions is a little secret between me and the nurse sister, no one else can guide,

(3) I volunteer to answer the nurse's questions. If I do not want to answer the nurse's questions, I can not answer at any time

Answer, and the nurse elder sister won't blame me, or like me equally.

Also, I declare that:

(1) I am willing to cooperate with the nurse sister to answer the nurse sister's questions;

(2) This informed consent form has been received.

Signature of the children:

Date: year month day time minutes

The researcher's statement

2. I have fully explained and explained to the subject the purpose of the clinical study, the study methods, operating procedures, and the possible risks and potential benefits of the subject's participation in the study, and answered all relevant questions of the subject satisfactorily.

Investigator (subject subject) signature: Contact:

Date: year month day time minutes