

CHILD ASSENT FORM

Study Title	A Multicenter Asparaginase Monitoring Study in patients with newly diagnosed Acute Lymphoblastic Leukemia (ALL)
Principal Investigator	Dr.
Study Site	

Introduction

You are currently receiving treatment for Acute Lymphoblastic Leukemia (ALL).

As part of your treatment, you will receive a medicine called PEG-asparaginase. The study mainly monitors the effectiveness of the drug during the entire treatment.

Doctors at are conducting a research study to better understand how this medicine works in children till the end of treatment.

Your parent or guardian has been given detailed information about this study. Because you are old enough to understand, we are also asking for your agreement (assent) to participate.

Why is this study being done?

PEG-asparaginase is an important drug used in treating leukemia.

In some patients:

- the drug may be cleared from the body faster, or
- the body may develop antibodies against the drug.

This study will help doctors understand:

- how much of the drug remains in the blood
- whether antibodies develop against the drug

What will happen if you participate?

You will continue to receive standard leukemia treatment as decided by your doctors.

This research study will not change your treatment.

The study mainly involves:

- collecting small blood samples to measure:
 - drug activity
 - antibodies against the drug may be checked if required

These blood samples will be collected during routine blood tests to avoid extra needle pricks. Additionally, drug related side effects will also be monitored as routine procedure.

Are there any risks?

The study does not involve giving any additional medicine.

The main risk related to blood sample collection, which may cause:

- mild pain from the needle
- bruising at the site of blood collection
- rarely infection

All samples will be collected by trained medical staff.

Are there any benefits?

You may or may not receive any direct benefit from participating in this study.

However, the results may help doctors better understand how this medicine works and improve treatment for children with leukemia in the future.

Do you have to participate?

Your participation is completely voluntary.

You can:

- choose not to participate
- withdraw from the study at any time

This will not affect your medical care or treatment.

Confidentiality

Your personal information will be kept confidential.

Your name will not appear in research reports or publications.

Contact Information

If you have questions about this study or experience any problems related to participation, please contact:

Principal Investigator

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Co-Investigator

.....

If you have questions about your rights as a research participant, you may contact:

Institutional Ethics Committee

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Study Title:

A Multicenter Asparaginase Monitoring Study in patients with newly diagnosed Acute Lymphoblastic Leukemia (ALL)

Identification Number _____

I confirm that:

1. I have read the information above (or it has been explained to me).

	Yes		No
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2. I understand what the study is about and I have had the opportunity to ask questions.

	Yes		No
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3. I understand the risks and potential benefits of this research study that were explained to me.

	Yes		No
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4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

	Yes		No
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5. I agree to have my samples used for study analysis or post hoc analysis.

	Yes		No
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6. I voluntarily agree to participate in this study.

	Yes		No
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7. By signing this form, I voluntarily agree for my participation in this study.

	Yes		No
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Signature/ Thumb impression of patient (<i>tick on appropriate option</i>)	Name of the patient	Date
Signature/ Thumb impression of a parent/guardian	Name of the parent	Date

Signature of the doctor obtaining the consent	Name of the doctor obtaining consent	Date
Signature/ Thumb impression of the LAR (<i>if applicable</i>)	Name of the LAR	Date
Address of the LAR (Capital letters) and contact details		
Signature of an impartial witness (<i>if applicable</i>)	Name of the impartial witness	Date
Address of the impartial witness (Capital letters) and contact detail		

A copy of duly signed and completed Assent Form shall be handed over to patient/guardian.

Signature of receiving: _____