

**PARENT INFORMATION SHEET (PIS)
AND
INFORMED CONSENT FORM (ICF)**

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

Introduction

Your child has been diagnosed with Acute Lymphoblastic Leukemia (ALL) and is currently receiving treatment at.....

We are inviting your child to participate in an investigator-initiated research study that will monitor the effectiveness of PEG-asparaginase during the entire phase of treatment.

In this document, the word “you” refers to the parent or legal guardian who is providing consent on behalf of the child.

Before you decide whether your child should participate, please read the following information carefully. You may ask the study doctor any questions.

Participation in this study is completely voluntary.

Purpose of the Study

PEG-asparaginase is an important medicine used in the treatment of ALL.

In some patients, the drug may become less effective over time because:

- the body clears the drug faster, or
- the body develops antibodies against the drug.

This study aims to better understand:

- the level of asparaginase enzyme activity in the blood
- whether antibodies develop against the drug

The information collected may help doctors improve treatment monitoring for children with ALL in the future.

Why is your child being invited?

Your child is being invited because:

- your child is diagnosed with Acute Lymphoblastic Leukaemia (ALL) and
- your child has/will receive PEG-asparaginase as part of treatment.

What will happen if your child participates?

Participation in this research study will not change your child's treatment plan.

The study will mainly involve:

1. Blood Sample Collection

Some additional blood samples may be collected during routine hospital visits to measure:

- asparaginase enzyme activity
- antibodies against asparaginase may be assessed if required

The blood samples will be taken at the same time as routine blood tests to avoid extra needle pricks.

2. Clinical Monitoring

Additionally, Doctors will monitor your child for possible side effects related to PEG-asparaginase such as:

- allergic reactions
- pancreatitis (inflammation of pancreas)
- clotting problems
- liver toxicity
- high blood sugar

These are already routinely monitored during treatment.

Duration of Participation

Your child will participate in this study from induction phase until completion of delayed intensification phase of treatment.

This usually lasts several months depending on the treatment schedule.

Possible Risks or Discomfort

This study does not involve giving any additional medicines beyond the standard treatment.

The only additional procedure may be blood sample collection.

Possible minor risks include:

- pain during needle insertion
- bruising at the blood draw site
- rarely infection at the needle site

All blood samples will be collected by trained medical staff.

Possible Benefits

If, during treatment, your child develops antibodies that reduce the effectiveness of pegaspargase, an alternative form of asparaginase may be offered, if available, to help ensure continued effective treatment. Besides that, your child may or may not receive any direct benefit from participating in this study.

However, the information collected may help doctors better understand how PEG-asparaginase works in children with ALL and improve treatment monitoring in the future.

Costs and Payments

Participation in this study will not involve any additional cost to you beyond the routine treatment expenses.

This study does not provide monetary payment for participation.

The medicine PEG-Asparaginase cost will be arranged by the patients at his/her own cost.

Confidentiality

Your child's personal information will be kept strictly confidential.

- Your child's name will not appear in research reports or publications.
- A study identification number will be used instead of personal details.
- Only authorized members of the research team, ethics committee, or regulatory authorities may review the records if required.

Voluntary Participation

Your child's participation in this study is completely voluntary.

You may choose not to participate, or you may withdraw your child from the study at any time, without giving any reason.

This decision will not affect your child's treatment or medical care in any way.

If you withdraw from the study, data collected up to that point may still be used for research analysis.

Contact Information

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

Principal Investigator

.....

Co-Investigator

.....

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

Institutional Ethics Committee

.....

INFORMED CONSENT FORM

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 and understood the information sheet provided for this study.

	Yes		No
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2. I have had the opportunity to ask questions and my questions have been answered.

	Yes		No
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3. I understand that participation in this study is voluntary.

	Yes		No
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4. I understand that I may withdraw my child from the study at any time without affecting my child's medical care.

	Yes		No
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5. I understand that my child's medical records may be reviewed by authorized persons for research and regulatory purposes.

	Yes		No
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6. I understand that my child's identity will remain confidential in any reports or publications.

	Yes		No
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7. I agree to allow blood samples collected for this study to be used for the analyses described in this study.

	Yes		No
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8. I have no objection to allow my child for taking part in the above study.

	Yes		No
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9. I have understood that toxicities due to PEG-asparaginase treatment, if any, will not be financially covered / compensated by the researchers.

	Yes		No
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By signing this form, I voluntarily agree for my child to participate in this study.

Signature/ Thumb impression of a parent (<i>tick on appropriate option</i>)	Signatory Name	Date
Signature/ Thumb impression of patient	Name of the patient	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 Parent Information Sheet (PIS) and completed Informed consent form (ICF) shall be handed over to the patient/guardian.

Signature of receiving: _____