

Life Science Case Report

CytoCell IVD FISH probes for acute lymphoblastic leukaemia diagnosis

ALLTogether1 – A treatment study protocol of the ALLTogether Consortium for children and young adults (0-45 years of age) with newly diagnosed acute lymphoblastic leukaemia (ALL) – Laboratory Study Protocol Guidelines

EU Clinical Trials Register EudraCT number 2018-001795-38 **CHIEF INVESTIGATOR:** MD PhD Mats Marshall Heyman, Karolinska University Hospital, Sweden

Introduction

The primary objective of ALLTogether¹ is to improve survival and quality of life in children and young adults with ALL. A sub-group of patients that may benefit from novel immunotherapy could be identified. The recruitment started in 2021 and will continue until at least May 2027.

The main treatment for ALL is chemotherapy, with a variety of drugs prescribed in different combinations, depending on the patient enrolled. Chemotherapy usually works well for children and young adults with ALL.

However, a better patient risk stratification would improve treatment plans and oncological outcomes, meaning less chemotherapy and reduced toxicity to patients in the low-risk group. The trial uses a combination of several factors to stratify patients into risk groups, determining the treatment they shall receive. This process includes investigating the cytogenetic abnormalities in leukaemic cells.^{1,2}

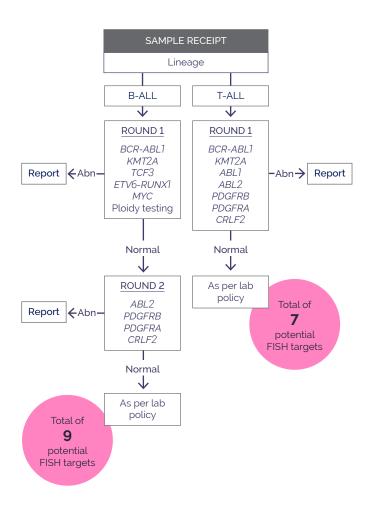


Figure 1 Acute lymphoblastic leukaemia FISH test algorithm

Probe name	Chromosome region	Cat. no.
IVDD PDGFRB Breakapart Probe	PDGFRB, 5q32, Red PDGFRB, 5q32, Green	LPH 031
IVDR BCR/ABL (ABL1) Translocation, Dual Fusion Probe	ABL1, 9q34.1, Red BCR, 22q11.2, Green	CE-LPH 007
IVDD TEL/AML1 (ETV6/RUNX1) Translocation, Dual Fusion Probe	TEL, 12p13.2, Red AML1, 21q22.1, Green	LPH 012
IVDR MLL (KMT2A) Breakapart Probe	MLL, 11q23.3, Red MLL, 11q23.3, Green	CE-LPH 013
IVDD E2A (TCF3)/PBX1 Plus Translocation, Dual Fusion Probe	E2A, 19p13.3, Green PBX1, 1q23.3, Red HLF, 17q22, Blue	LPH 080

Table 1 CytoCell® IVD products that support the ALLTogether¹ genetic risk stratification algorithm protocol implementation

Probe name	Chromosome region	Cat. no.
RUO PDGFRB/CSF1R Breakapart Probe	5q32, Red 5q32, Green 5q32, Aqua	MPH51700
RUO ABL2 Breakapart/TP53 Deletion Probe	1q25.2, Red 1q25.2, Green 17p13.1, Aqua	MPH51680
RUO JAK2 Breakapart Probe	9p24.1, Red 9p24.1, Green	MPD2680
RUO MLL/AFF1 Breakapart/Dual Fusion Probe	11q23.3, Red 11q23.3, Green 4q21.3-4q22.1, Aqua	MPH22100
RUO CRLF2/P2RY8/IGH Plus Deletion/Breakapart Probe	Xp22.33/ Yp11.32, Red Xp22.33/ Yp11.32, Aqua 14q32.33, Green	MPH51690
RUO IGK/IGL/MYC Dual Fusion Probe	IGK, 2p11.2, Aqua IGL, 22q11.21-q11.23, Green MYC, 8q24.21, Red	MPP4350
RUO IGK/c-MYC Dual Fusion Probe	IGK, 2p11.2, Green c-MYC, 8q24.21, Red	MPD4490
RUO IGL/c-MYC Dual Fusion Probe	IGL, 22q11.22-q11.23, Green c-MYC, 8q24.21, Red	MPD4480
IVDD IGH/MYC Translocation, Dual Fusion Probe	IGH, 14q32.33, Green MYC, 8q24.21, Red	LPS 035

 $\textbf{Table 2} \ \ \textbf{Other CytoCell probes and CytoCell myProbes} \\ \text{@}, custom \ \ \textbf{FISH probes that may aid in ALL research} \\ \text{\ }$

References

1 EU Clinical Trials Register. Identifier 2018-001795-38, ALLTogether1- A Treatment study protocol of the ALLTogether Consortium for children and young adults (0-45 years of age) with newly diagnosed acute lymphoblastic leukaemia (ALL). Available at: https://www.clinicaltrialsregister.eu/ctr-search/search?query=2018-001795-38 (Accessed August 2024). 2 ClinicalTrials.gov. Identifier NCT00287391, ALLTogether1- A Treatment Study Protocol of the ALLTogether Consortium for Children and Young Adults (0-45 Years of Age) With Newly Diagnosed Acute Lymphoblastic Leukaemia (ALL). Available at: https://clinicaltrials.gov/study/NCT04307576 (Accessed August 2024).

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