

# DGI-027. Effectiveness and safety of clofarabine in pediatric patients with acute leukemia

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Clofarabine is a purine nucleoside antimetabolite second generation antineoplastic indicated for the treatment of acute lymphoblastic leukemia in pediatric patients ( $\leq 21$  years) who have relapsed or are refractory after receiving at least two prior regimens and who have no other treatment option which provides a durable response.

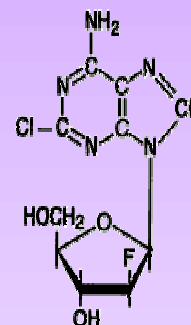
Despite progress in leukemia therapy, most children who experience relapse have a dismal prognosis. New effective approaches are needed.

## OBJECTIVE

To assess the effectiveness and safety of clofarabine in pediatric patients with refractory or relapsed acute leukemia.

## STUDY DESIGN AND METHODS

- Observational retrospective study.
- Patients included: pediatric patients ( $\leq 21$  years) diagnosed with acute leukemia who received clofarabine as antineoplastic treatment during 2007-2011.
- Collected data: number of patients, age, sex, weight, height and treatment schemes lines administered prior to clofarabine (Oncofarm® programme).
- Medical records used as a source of safety data regarding potential adverse reactions due to clofarabine.

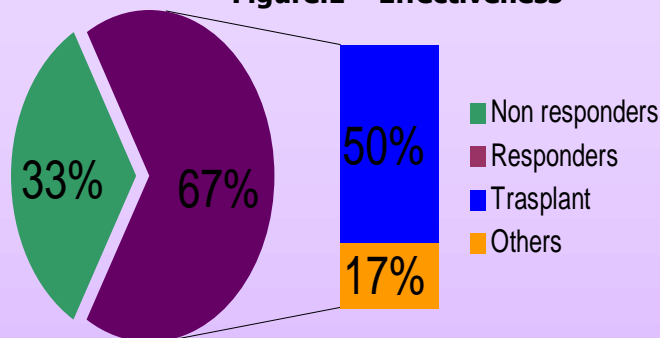


## RESULTS

Characteristics	n
Patients	6
Age (years), median	11,5 (5-16)
Sex (M/F)	4/2
Diagnose	
ALL <sup>a</sup> refractory	3/6
ALL <sup>a</sup> relapsed	2/6
AML <sup>b</sup> refractory	1/6
Prior administered regimens (median)	2 (1-4)
Scheme for treatment	
Clofarabine 52 mg/m <sup>2</sup>	1/6
Clofarabine 40 mg/m <sup>2</sup> (SHOP 2008)	5/6
Administered cycles (median)	2 (1-2)

a: Acute Lymphoblastic Leukemia; b: Acute Myeloid Leukemia

Figure.1 Effectiveness



Adverse reactions	n
Pancytopenia	2/6
Mucositis Grade IV	1/6
Flushing	1/6
Transaminase elevation	6/6

## CONCLUSION

The administration of clofarabine allowed to reach transplantation in 50% of patients with acceptable toxicity, favouring the appearance of possible durable responses.