



# REAL-LIFE IMPACT OF INCLUDING MONTELUKAST AS PREMEDICATION ON THE INCIDENCE OF INFUSION-RELATED REACTIONS TO ISATUXIMAB AND DESCRIPTION OF RISK FACTORS

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## BACKGROUND AND IMPORTANCE

One of the most common adverse reactions related to the use of isatuximab are infusion reactions (IRRs). These IRRs can lead to the termination of isatuximab treatment. To minimize these IRRs, the technical file recommends the administration of dexamethasone, paracetamol and diphenhydramine as premedication.

The inclusion of Montelukast in the above premedication regimen could improve the tolerability of the infusion, analogously to what happened with daratumumab.



## AIM AND OBJECTIVES

**Primary objective:** Evaluate the impact of including montelukast as premedication on the incidence of infusion reactions associated with isatuximab administration.

**Secondary objectives:**

- Description of the incidence of infusion reactions in daily clinical practice.
- Evaluation of the influence of possible risk factors: allergies, previous infusions with isatuximab and the concentration of the bag to be infused.

## MATERIALS AND METHODS



Multicentric retrospective study conducted in one secondary and three tertiary hospitals.

- Odds ratios (OR) and Mann-Whitney U tests were calculated to evaluate qualitative and quantitative risk factors respectively.
- Absolute risk reduction (ARR) and number needed to treat (NNT) were used to assess the impact of montelukast as premedication.

### Inclusion criteria

- ✓ Patients who had received isatuximab.

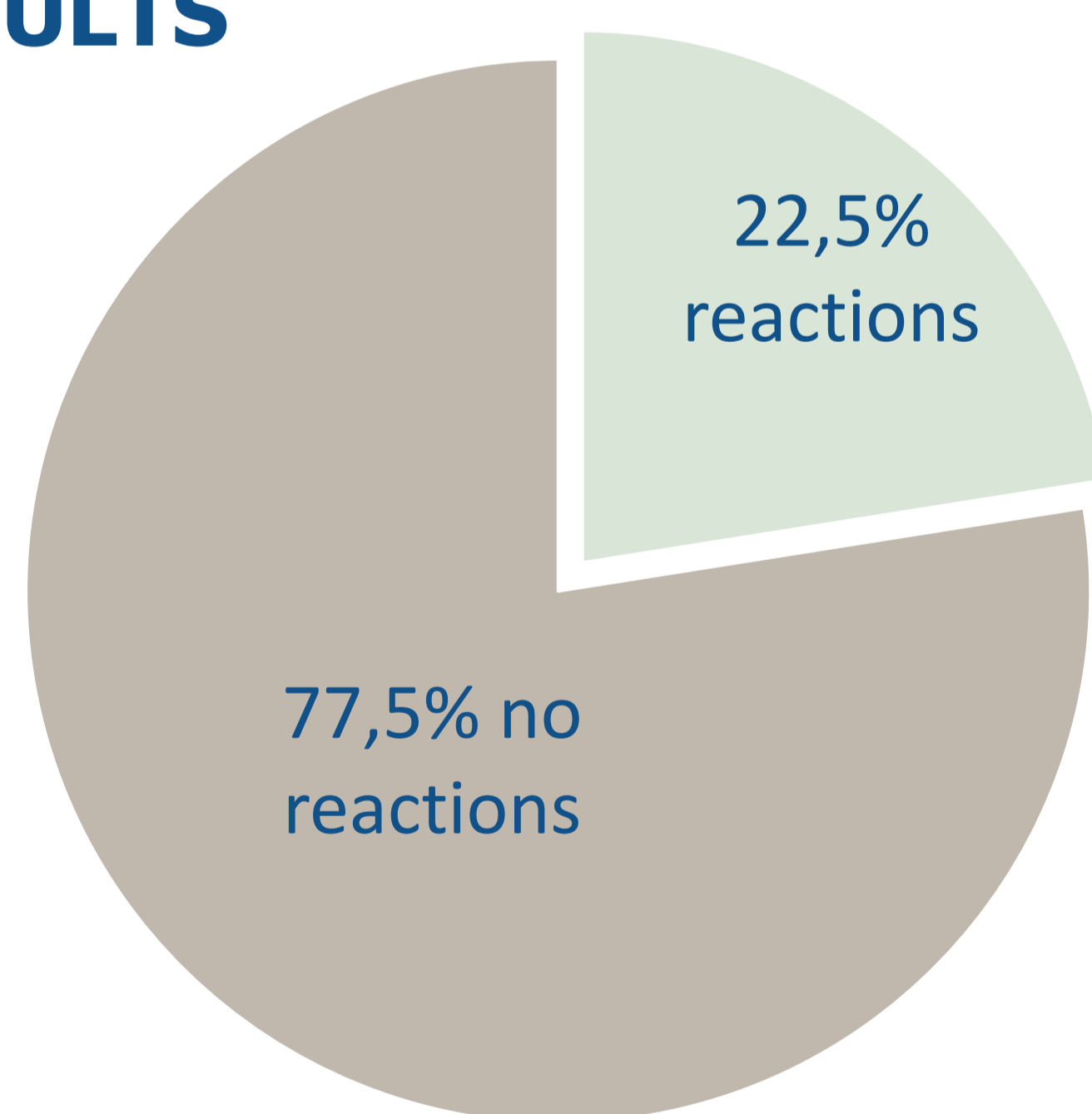
Follow-up was carried out until September 2023, treatment discontinuation or death.

**Variables collected:** Sex, age, treatment regimen, premedication regimen, number of isatuximab doses and occurrence of IRR.

### Exclusion criteria:

- ✗ Patients who had received isatuximab in clinical trials.
- ✗ Patients who had received isatuximab with corticosteroids as off-label premedication.

## RESULTS



40 patients were included.  
60% was men. Median age 66 (54 – 72) years.

Incidence of IRRs, patients premedicated <b>with</b> montelukast 32,5%	7,69% IRRs
	92,31% <u>without</u> IRRs
Incidence of IRRs, patients premedicated <u>without</u> montelukast 32,5%	29,63 % IRRs
	70,37 % <u>without</u> IRRs

- OR was 0.20 (95%CI 0.02 – 1.79).
- ARR was 0.22 (95%CI -0.01 – 0.44).
- NNT was 5.
- All IRRs were in the first infusion.
- No IRR were found for second or further doses in any patient, no risk factors were found.



## CONCLUSION AND RELEVANCE

In our experience, iIRR observed for isatuximab was lower compared to pivotal clinical trials. The inclusion of montelukast as premedication could reduce IRR, which should be confirmed in subsequent studies.

