**USE OF DARATUMUMAB BASED TREATMENTS IN PATIENTS WITH MULTIPLE MYELOMA AND HEPATIC IMPAIRMENT**

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**BACKGROUND**

- There is literature -subgroup analysis- suggesting lack of benefit for daratumumab drug combinations in patients with untreated multiple myeloma (MM) and hepatic impairment (Hi).

To conduct a systematic search and methodological interpretation of subset analysis about the use of daratumumab-based treatments in patients with untreated MM and Hi.

**AIM**

- Review strategy in “Clinical Queries/Narrow” tool: (Therapy/Narrow[filter]) AND (daratumumab AND myeloma)
- Inclusion criteria: Randomized clinical trials (RCTs) with subset analyzes according to baseline hepatic function for overall survival (OS) or progression-free survival (PFS)
- Two methodologies
  1. Consideration of heterogeneity of subgroups (p<0.1), prespecification, biological support and consistency
  2. Validated tool with preliminary questions to discard subgroup analyzes without minimal relevance and checklist → Recommendations of applicability

**MATERIAL AND METHODS**

- Bibliographic review in Pubmed® (October 11, 2020)

Results of bibliographic review:

- 25 results
- 22 results excluded
- 3 RCTs included

**RESULTS**

- Heterogeneity of subgroups: statistical interaction among subsets was observed for PFS in 1 RCT.
- Pre-specification: subgroups pre-specified in each endpoint of all RCTs
- Biological support: It was reasoned in all RCTs.
- Consistency: No consistency of these subset analysis was found

**CONCLUSION**

No differences in OS or PFS according to baseline hepatic function should be considered for daratumumab-based combinations in patients with untreated MM. Patients with normal hepatic function and HI could benefit from treatment. Application of subgroup analysis should be considered with caution.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**