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Characteristics of Clinical Trials for Multiple Myeloma and CAR-T Cell Therapy: A Cross Sectional Analysis

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Background:
In recent decades novel CAR-T cell therapies have proven efficacious in the treatment of multiple myeloma, leading to FDA approval. As CAR-T cell therapies continue to be developed in clinical trials, it is important to assess trends over time that can inform drug development and relate to equitable access and representation. This cross-sectional study was conducted to analyze the characteristics of clinical studies for multiple myeloma and CAR-T cell therapy registered in ClinicalTrials.gov (CTG).

Methods:
All multiple myeloma clinical studies registered on CTG from September 27, 2007 to July 15, 2023 were identified using Advanced Search feature in ClinicalTrials.gov. Trial characteristics were assessed through relative frequency calculations. Odds ratio and 95% confidence intervals were determined for key characteristics and significance of findings.

Results:
Out of the 390,301 studies registered in CTG during this period, a mere 0.63% (2,457 studies) were conducted for multiple myeloma, compared to 1.61% (6,287 studies) for lymphoma and 1.46% (5,699 studies) for leukemia. Among these multiple myeloma studies, 85.47% (2,100 studies) were interventional and 14.82% (364 studies) were observational. Further, a total of 184 studies for CAR-T cell therapy in multiple myeloma were found in CTG registered during this period. Among these, 124 studies are still ongoing, constituting around 12.53% of the total 990 ongoing multiple myeloma studies.
In multiple myeloma, around 51.98% (1276 studies) were industry sponsored, while 12.75% (313 studies) received funding from the National Institutes of Health (NIH) and other U.S. federal agencies (FA). The remaining 36.7% (901 studies) were funded by all others including individuals, universities and other research organizations. Similar funding trends were observed for 984 ongoing clinical studies.
Notably, there were statistically significant differences in funding trends for CAR-T cell therapy within multiple myeloma studies. Industry funded a higher percentage for CAR-T cell therapy, 66.3%, compared to the overall 51.98% multiple myeloma studies that were industry sponsored. Further, NIH/ FA provided funding in 12.5% studies for CAR-T for CAR-T cell therapy, compared to a much lower 4.9% of all multiple myeloma studies.
Interestingly, the premature discontinuation rates for CAR-T cell therapy clinical studies in multiple myeloma were significantly lower than those observed in overall multiple myeloma studies (OR 0.33; CI 0.177 to 0.611; $p<0.01$). This is promising for adherence in a heavily pretreated population. However, the proportion of studies with unknown status were significantly higher when compared to the overall multiple myeloma studies. (OR 2.84; 95% CI 1.94 to 4.18; $p<0.01$). There was no statistically significant difference between the unknown status and premature discontinuation rates of CAR-T cell therapy studies in multiple myeloma are myeloma compared to those in lymphoma.

Conclusion:
This cross-sectional study demonstrates that CAR T-cell therapy for multiple myeloma remains of prominent interest to industry followed by NIH and other U.S. funding organizations. There were significant trends noted that can inform drug development policy and relate to access and representation in trials. While the trends in the study discontinuation trends are promising, there is a need to address the proportion of studies with unknown status. Improved reporting and research into clinical trial funding and design will optimize efforts in developing cellular therapies for patients with myeloma.

Disclosures No relevant conflicts of interest to declare.

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