Regulatory, Financial and Access Considerations

APPLICATION OF ICTIS TO CURRENTLY RECRUITING CLINICAL TRIALS: A NOVEL SCORING SYSTEM TO ASSESS THE INCLUSIVITY OF ADVANCED NON-SMALL-CELL LUNG CANCER IMMUNOTHERAPY TRIALS

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Background

Many immunotherapy trials contain overly restrictive or irrelevant exclusionary criteria, limiting accessibility to patients and contributing to disparities in enrollment and outcomes. We developed a novel scoring system, the Immunotherapy Clinical Trial Inclusivity Scale (ICTIS), to measure the inclusivity of immunotherapy clinical trials and provide recommendations for broadening eligibility criteria for future immunotherapy trials. Using ICTIS, we measured the restrictiveness of eligibility criteria across advanced non-small-cell lung cancer (NSCLC) immunotherapy clinical trials.

Methods

National guidelines and novel author recommendations informed ICTIS’s development, a 22-point summative scale using a binary system awarding 1 point for the usage of each inclusive criterion. Recruiting and not-yet-recruiting NSCLC interventional U.S. trials were accessed using ClinicalTrials.gov. Trials were filtered through to identify and record eligibility criteria information on only metastatic immunotherapy NSCLC trials. Then, these trials were scored with ICTIS and compared in subgroups: year, combination treatment type, phase of trial, and line of treatment. Mean ICTIS scores were compared with ANOVA and t-tests, and individual points were compared with chi-squared tests.

Results

142 out of 343 trials from ClinicalTrials.gov were metastatic and immunotherapy and scored. The majority of trials still used exclusive criteria for performance status, pneumonitis, washout period, and various organ function criteria. Through subgroup analyses, phase ½ trials were found to have significantly more exclusive psychiatric and cardiac criteria ($\chi^2=7.3; p<0.05$). Use of platelet count target was used in significantly more number of immunotherapy studies than in combination studies ($\chi^2=5.1; p<0.01$). Taking date of registration of clinical trial into consideration, we noted that leptomeningeal involvement became more inclusive over time ($\chi^2=8.0; p<0.05$). A significantly higher number of second-line trials had inclusive pneumonitis criteria ($\chi^2=4.9; p<0.05$). However, the majority of criteria were uniform different risk profiles ($\chi^2; p>0.05$). No significant differences were found between mean ICTIS scores across all subgroups (ANOVA and t-test; $p>0.05$). Also, a wide distribution of scores was found showing low homogeneity (figure 1).

Conclusions

Our results indicate that despite the release of national guidelines for improving inclusivity, immunotherapy trials have made negligible efforts to broaden their rigid eligibility criteria. Moreover, the majority of trials, irrespective of combination or monotherapies, first-line or subsequent-line, and early or late phase have homogenous criteria across various eligibility parameters. Using ICTIS, metastatic NSCLC immunotherapy trials were able to be analyzed for their inclusivity and prevalent restrictive criteria were identified for refinement. Our analysis can help investigators design immunotherapy studies to improve patient access and the generalizability of results.

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