Building an Ethics Foundation for Future Spinal Cord Injury Clinical Trials

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METHODS

- ClinicalTrials.gov mined for SCI clinical trials registered up to December 2022 using the search term "spinal cord injury" and variants.
- Inclusion and exclusion criteria manually populated for each trial and coded using thematic analysis.
- Criteria cross-coded with geographical region and intervention type.

RESULTS

Figure 1: Distribution of exclusion criteria across trial phases. Solid black bars - total number of trials assessed for the identified phase. Dotted bars - number of trials that exclude participants on the basis of reproductive potential. Black slanted line bars - exclusion for mental illness. Hatched bars - exclusion for substance use. Black fish-scaled bars - exclusion at the investigator's discretion.

<table>
<thead>
<tr>
<th>Phase</th>
<th>North America</th>
<th>Asia</th>
<th>Europe</th>
<th>Multi-site</th>
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</thead>
<tbody>
<tr>
<td>Early Phase</td>
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<td>15</td>
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<td>5</td>
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<tr>
<td>Phase I</td>
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<td>Phase II</td>
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<td>Phase III</td>
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<td>33</td>
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<td>Phase IV</td>
<td>71</td>
<td>25</td>
<td>20</td>
<td>10</td>
</tr>
</tbody>
</table>

Table 1: Heat map of exclusion criteria distribution by trial phase, intervention type, and geographic region. Values are represented as percentages of the total number of trials registered as that intervention type, in the specified region and phase.

ACKNOWLEDGEMENTS

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OBJECTIVE

To examine the landscape of participation criteria for spinal cord injury (SCI) clinical trials registered on ClinicalTrials.gov.

BACKGROUND

- There are 250,000 – 500,000 SCI cases worldwide each year.¹
- The incidence of depression and anxiety can be as high as 40%, and 20% for substance use in people with lived experience (PWLE) of SCI.²
- Numerous interventions – biologicals, drugs, devices, procedural, rehabilitation, or a combination – have improved quality of life but none have provided a solution.
- Potential trial participants rely on the public database, ClinicalTrials.gov, for information on novel interventions and ongoing clinical trials.

DISCUSSION

- Inconsistent phase designation and intervention categorization challenge usability of the database.
- Fewer than 15% of trials benchmarked criteria for mental illness and substance use to clinical assessments. This is both a serious scientific and ethical concern, and pose a challenge to powering trials from a limited participant pool.
- Leaving undefined criteria to the investigator’s discretion lacks transparency and leaves room for biases.
- Drug trials overall and trials conducted in Europe were more likely to exclude participants on the basis of reproductive potential, mental illness, substance use, and at the investigator’s discretion.
- Review of participation criteria for future SCI trials is needed to meet the goals of both ethical and scientific rigor.

REFERENCES


RELATED PUBLICATIONS