Premature Discontinuation of Randomized Trials in Critical and Emergency Care: A Retrospective Cohort Study

Por: Schandelmaier, S (Schandelmaier, Stefan)¹,²; von Elm, E (von Elm, Erik)³; You, JJ (You, John J.)⁴,⁵; Blumle, A (Blumle, Anette)⁶; Tomonaga, Y (Tomonaga, Yuki)⁷; Lamontagne, F (Lamontagne, Francois)⁸; Saccilotto, R (Saccilotto, Ramon)⁹; Amstutz, A (Amstutz, Alain)¹⁰; Bengough, T (Bengough, Theresa)¹¹; Meerpohl, JJ (Meerpohl, Joerg J.)¹²

CRITICAL CARE MEDICINE
Volumen: 44
Número: 1
Páginas: 130-137
DOI: 10.1097/CCM.0000000000001369
Fecha de publicación: JAN 2016
Ver información de revista

Resumen

Objectives: Randomized clinical trials that enroll patients in critical or emergency care (acute care) setting are challenging because of narrow time windows for recruitment and the inability of many patients to provide informed consent. To assess the extent that recruitment challenges lead to randomized clinical trial discontinuation, we compared the discontinuation of acute care and nonacute care randomized clinical trials.

Design: Retrospective cohort of 894 randomized clinical trials approved by six institutional review boards in Switzerland, Germany, and Canada between 2000 and 2003.

Setting: Randomized clinical trials involving patients in an acute or nonacute care setting.

Subjects and Interventions: We recorded trial characteristics, self-reported trial discontinuation, and self-reported reasons for discontinuation from protocols, corresponding publications, institutional review board files, and a survey of investigators.

Measurements and Main Results: Of 894 randomized clinical trials, 64 (7%) were acute care randomized clinical trials (29 critical care and 35 emergency care). Compared with the 830 nonacute care randomized clinical trials, acute care randomized clinical trials were more frequently discontinued (28 of 64, 44% vs 221 of 830, 27%; p = 0.004). Slow recruitment was the most frequent reason for discontinuation, both in acute care (13 of 64, 20%) and in nonacute care randomized clinical trials (7 of 64, 11%). Logistic regression analyses suggested the acute care setting as an independent risk factor for randomized clinical trial discontinuation specifically as a result of slow recruitment (odds ratio, 4.00; 95% CI, 1.72-9.31) after adjusting for other established risk factors, including nonindustry sponsorship and small sample size.
Conclusions: Acute care randomized clinical trials are more vulnerable to premature discontinuation than nonacute care randomized clinical trials and have an approximately four-fold higher risk of discontinuation due to slow recruitment. These results highlight the need for strategies to reliably prevent and resolve slow patient recruitment in randomized clinical trials conducted in the critical and emergency care setting.

Palabras clave

Palabras clave de autor: critical care; early termination of clinical trials; emergency medicine; ethics committees; randomized controlled trials

KeyWords Plus: CLINICAL-TRIALS; RECRUITMENT; ENROLLMENT; MULTICENTER; CHALLENGES; FAILURE; LESSONS; SHOCK

Información del autor

Dirección para petición de copias: Briel, M (autor para petición de copias)


Direcciones:

+ [6] Univ Freiburg, Med Ctr, German Cochrane Ctr, Freiburg, Germany
+ [7] Univ Zurich, Epidemiol Biostat & Prevent Inst, Zurich, Switzerland
+ [8] Univ Sherbrooke, CHU Sherbrooke, Ctr Rech Clin, Sherbrooke, PQ J1K 2R1, Canada
+ [9] Austrian Fed Inst Hlth Care, Dept Hlth & Soc, Vienna, Austria
+ [10] Helsinki Univ Hosp, Dept Urol, Helsinki, Finland
+ [12] Univ Helsinki, Helsinki, Finland
+ [13] Pontificia Univ Catolica Chile, Dept Internal Med, Santiago, Chile
+ [14] Univ Chile, Fac Dent, Evidence Based Dent Unit, Santiago, Chile
+ [16] Amer Univ Beirut, Dept Internal Med, Beirut, Lebanon
Direcciones de correo electrónico: Matthias.Briel@usb.ch

Financiación

<table>
<thead>
<tr>
<th>Entidad financiadora</th>
<th>Número de concesión</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swiss National Science Foundation</td>
<td>320030_133540/1</td>
</tr>
<tr>
<td>Brocher Foundation</td>
<td></td>
</tr>
<tr>
<td>Research Early Career Award from Hamilton Health Sciences</td>
<td></td>
</tr>
<tr>
<td>German Research Foundation</td>
<td>EL 544/1-2</td>
</tr>
<tr>
<td>Academy of Finland</td>
<td></td>
</tr>
<tr>
<td>Finnish Cultural Foundation</td>
<td></td>
</tr>
<tr>
<td>Finnish Medical Foundation</td>
<td></td>
</tr>
<tr>
<td>Jane and Aatos Erkko Foundation</td>
<td></td>
</tr>
<tr>
<td>Sigrid Juse’lius Foundation</td>
<td></td>
</tr>
<tr>
<td>Hamilton Health Sciences Foundation</td>
<td></td>
</tr>
<tr>
<td>FP7 grant</td>
<td></td>
</tr>
</tbody>
</table>
Ver texto de financiación

Editorial

LIPPINCOTT WILLIAMS & WILKINS, TWO COMMERCE SQ, 2001 MARKET ST, PHILADELPHIA, PA 19103 USA

Categorías / Clasificación

Áreas de investigación: General & Internal Medicine
Categorías de Web of Science: Critical Care Medicine

Información del documento

Tipo de documento: Article
Idioma: English
Número de acceso: WOS:000366605100015
ISSN: 0090-3493
eISSN: 1530-0293

Información de la revista

Impact Factor: Journal Citation Reports®

Otra información

Número IDS: CY7QZ
Referencias citadas en la Colección principal de Web of Science: 19
Veces citado en la Colección principal de Web of Science: 0