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(Bluemle, Anette)[6]; Tomonaga, Y (Tomonaga, Yuki)[7]; Lamontagne, F (Lamontagne, Francois)[8]; Saccilotto, R (Saccilotto, Ramon)[1]; Amstutz, A (Amstutz, Alain)[1]; Bengough, T (Bengough, Theresa)[9]; Meerpohl, JJ (Meerpohl, Joerg J.)[6] ...Más

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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)

Univ Basel Hosp, Dept Clin Res, Basel Inst Clin Epidemiol & Biostat, CH-4031 Basel, Switzerland.

Direcciones:

[1] Univ Basel Hosp, Dept Clin Res, Basel Inst Clin Epidemiol & Biostat, CH-4031 Basel, Switzerland

[2] Univ Basel Hosp, Dept Med, Acad Swiss Insurance Med, CH-4031 Basel, Switzerland

[3] Univ Lausanne Hosp, Cochrane Switzerland, Inst Social & Prevent Med IUMSP, Lausanne, Switzerland

[4] McMaster Univ, Dept Clin Epidemiol & Biostat, Hamilton, ON, Canada

[5] McMaster Univ, Dept Med, Hamilton, ON, Canada

[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

[11] Helsinki Univ Hosp, Dept Publ Hlth, 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

[15] McMaster Univ, Michael G DeGroote Inst Infect Dis Res, Hamilton, ON, Canada

[16] Amer Univ Beirut, Dept Internal Med, Beirut, Lebanon

[17] SUNY Buffalo, Dept Med, Buffalo, NY 14260 USA
[18] Sichuan Univ, West China Hosp, Chinese Evidence Based Med Ctr, Chengdu 610064, Peoples R China
[19] Univ Zurich, Univ Zurich Hosp, Dept Neonatol, Zurich, Switzerland
[20] McMaster Univ, Dept Anesthesia, Hamilton, ON, Canada
[21] McMaster Univ, Michael G DeGroote Inst Pain Res & Care, Hamilton, ON, Canada
[22] Vall dHebron Hosp, Dept Cardiol, Epidemiol Unit, Barcelona, Spain
[23] CIBERESP, Barcelona, Spain
[24] Univ Hosp Bern, Inst Nucl Med, CH-3010 Bern, Switzerland
[25] Orthoped Inst Galeazzi, Ist Ricovero & Cura Carattere Sci, Milan, Italy
[26] Univ Basel Hosp, Dept Surg, CH-4031 Basel, Switzerland
[27] Hosp Sick Children, Res Inst, Dept Anesthesia & Pain Med, Toronto, ON M5G 1X8, Canada
[28] Stanford Univ, Stanford Prevent Res Ctr, Stanford, CA 94305 USA
[29] Innlandet Hosp Trust, Div Gjovik, Dept Med, Oppland, Norway
[30] Univ Toronto, Inst Hlth Policy Management & Evaluat, Toronto, ON, Canada
[31] Royal Marsden Hosp, Dept Med Oncol, London SW3 6JJ, England
[32] Univ Basel Hosp, Dept Oncol, CH-4031 Basel, Switzerland

Direcciones de correo electrónico: Matthias.Briel@usb.ch

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