



Enteral versus parenteral early nutrition in ventilated adults with shock: a randomised, controlled, multicentre, open-label, parallel-group study (NUTRIREA-2)

Submitted by Beatrice Guillaumat on Wed, 08/28/2019 - 14:39

Titre	Enteral versus parenteral early nutrition in ventilated adults with shock: a randomised, controlled, multicentre, open-label, parallel-group study (NUTRIREA-2)
Type de publication	Article de revue
Auteur	Reignier, Jean [1], Boisramé-Helms, Julie [2], Brisard, Laurent [3], Lascarrou, Jean-Baptiste [4], Ait Hssain, Ali [5], Anguel, Nadia [6], Argaud, Laurent [7], Asehnoune, Karim [8], Asfar, Pierre [9], Bellec, Frédéric [10], Botoc, Vlad [11], Bretagnol, Anne [12], Bui, Hoang-Nam [13], Canet, Emmanuel [14], Da Silva, Daniel [15], Darmon, Michael [16], Das, Vincent [17], Devaquet, Jérôme [18], Djibre, Michel [19], Ganster, Frédérique [20], Garrouste-Orgeas, Maité [21], Gaudry, Stéphane [22], Gontier, Olivier [23], Guerin, Claude [24], Guidet, Bertrand [25], Guitton, Christophe [26], Herbrecht, Jean-Etienne [27], Lacherade, Jean-Claude [28], Letocart, Philippe [29], Martino, Frédéric [30], Maxime, Virginie [31], Mercier, Emmanuelle [32], Mira, Jean-Paul [33], Nseir, Saad [34], Piton, Gael [35], Quenot, Jean-Pierre [36], Richecoeur, Jack [37], Rigaud, Jean-Philippe [38], Robert, René [39], Rolin, Nathalie [40], Schwebel, Carole [41], Sirodot, Michel [42], Tinturier, François [43], Thévenin, Didier [44], Giraudeau, Bruno [45], Le Gouge, Amélie [46]
Organisme	NUTRIREA-2 Trial Investigators [47], Clinical Research in Intensive Care and Sepsis (CRICS) group [48]
Editeur	Lancet Publishing Group
Type	Article scientifique dans une revue à comité de lecture
Année	2018
Langue	Anglais
Date	13 Janvier 2018
Numéro	10116
Pagination	133-143
Volume	391
Titre de la revue	Lancet
ISSN	1474-547X
Mots-clés	Adult [49], Aged [50], critical care [51], enteral nutrition [52], Female [53], Hospital Mortality [54], Humans [55], Length of Stay [56], Male [57], Middle Aged [58], Parenteral Nutrition [59], Respiration, Artificial [60], Shock [61], Time Factors [62], Treatment Outcome [63], Vasoconstrictor Agents [64]

BACKGROUND: Whether the route of early feeding affects outcomes of patients with severe critical illnesses is controversial. We hypothesised that outcomes were better with early first-line enteral nutrition than with early first-line parenteral nutrition. **METHODS:** In this randomised, controlled, multicentre, open-label, parallel-group study (NUTRIREA-2 trial) done at 44 French intensive-care units (ICUs), adults (18 years or older) receiving invasive mechanical ventilation and vasopressor support for shock were randomly assigned (1:1) to either parenteral nutrition or enteral nutrition, both targeting normocaloric goals (20-25 kcal/kg per day), within 24 h after intubation. Randomisation was stratified by centre using permutation blocks of variable sizes. Given that route of nutrition cannot be masked, blinding of the physicians and nurses was not feasible. Patients receiving parenteral nutrition could be switched to enteral nutrition after at least 72 h in the event of shock resolution (no vasopressor support for 24 consecutive hours and arterial lactate <2 mmol/L). The primary endpoint was mortality on day 28 after randomisation in the intention-to-treat-population. This study is registered with ClinicalTrials.gov, number NCT01802099.

Résumé en anglais

FINDINGS: After the second interim analysis, the independent Data Safety and Monitoring Board deemed that completing patient enrolment was unlikely to significantly change the results of the trial and recommended stopping patient recruitment. Between March 22, 2013, and June 30, 2015, 2410 patients were enrolled and randomly assigned; 1202 to the enteral group and 1208 to the parenteral group. By day 28, 443 (37%) of 1202 patients in the enteral group and 422 (35%) of 1208 patients in the parenteral group had died (absolute difference estimate 2·0%; [95% CI -1·9 to 5·8]; p=0·33). Cumulative incidence of patients with ICU-acquired infections did not differ between the enteral group (173 [14%]) and the parenteral group (194 [16%]; hazard ratio [HR] 0·89 [95% CI 0·72-1·09]; p=0·25). Compared with the parenteral group, the enteral group had higher cumulative incidences of patients with vomiting (406 [34%] vs 246 [20%]; HR 1·89 [1·62-2·20]; p<0·0001), diarrhoea (432 [36%] vs 393 [33%]; 1·20 [1·05-1·37]; p=0·009), bowel ischaemia (19 [2%] vs five [<1%]; 3·84 [1·43-10·3]; p=0·007), and acute colonic pseudo-obstruction (11 [1%] vs three [<1%]; 3·7 [1·03-13·2]; p=0·04).

INTERPRETATION: In critically ill adults with shock, early isocaloric enteral nutrition did not reduce mortality or the risk of secondary infections but was associated with a greater risk of digestive complications compared with early isocaloric parenteral nutrition.

FUNDING: La Roche-sur-Yon Departmental Hospital and French Ministry of Health.

URL de la notice

<http://okina.univ-angers.fr/publications/ua20129> [65]

DOI

10.1016/S0140-6736(17)32146-3 [66]

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Autre titre

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Identifiant

(ID) PubMed 29128300 [68]

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