

PARACETAMOL VERSUS IBUPROFEN FOR TREATMENT OF PERSISTENT DUCTUS ARTERIOSUS CLOSURE IN PRETERM INFANTS: IBUPAR-TRIAL

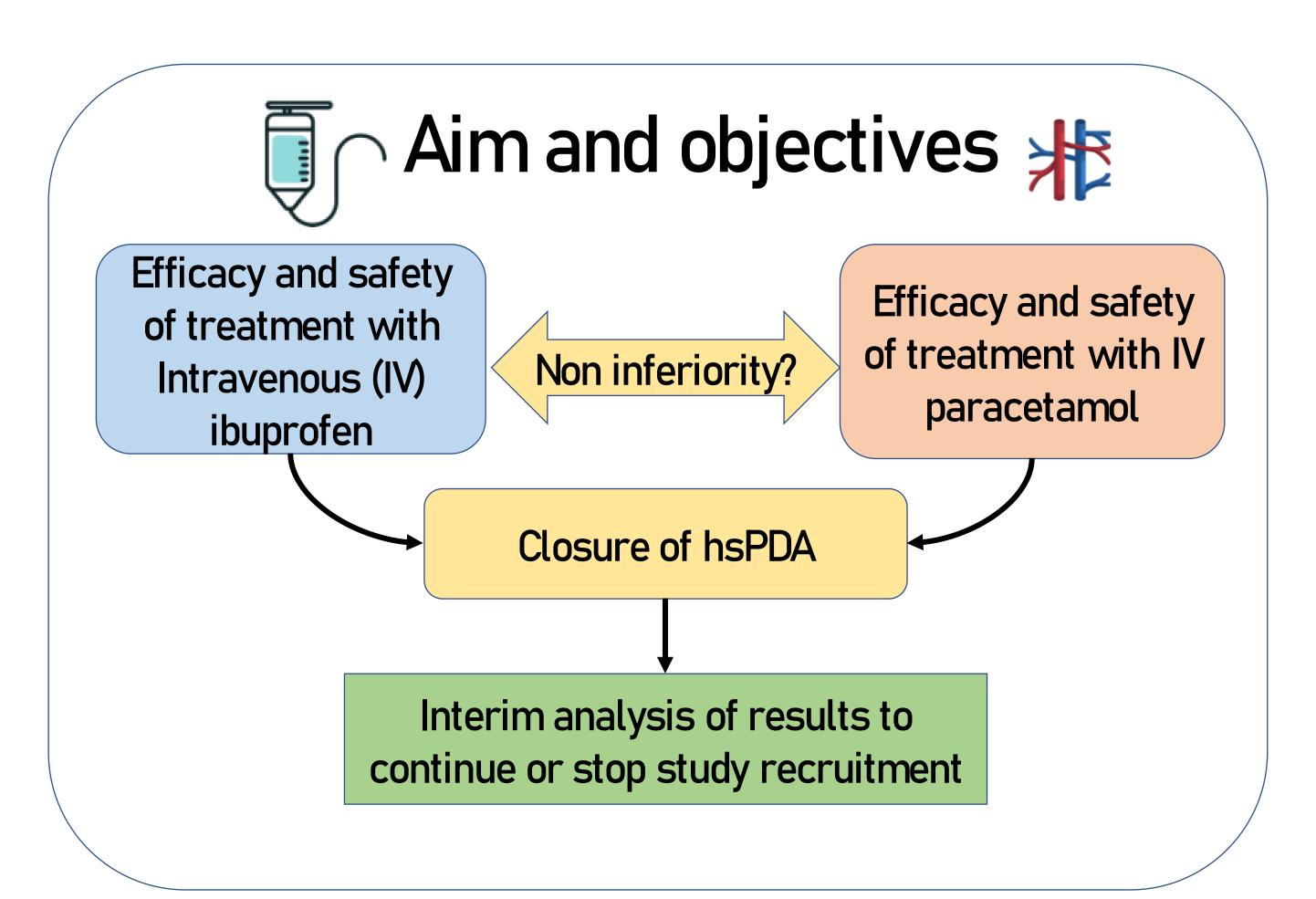


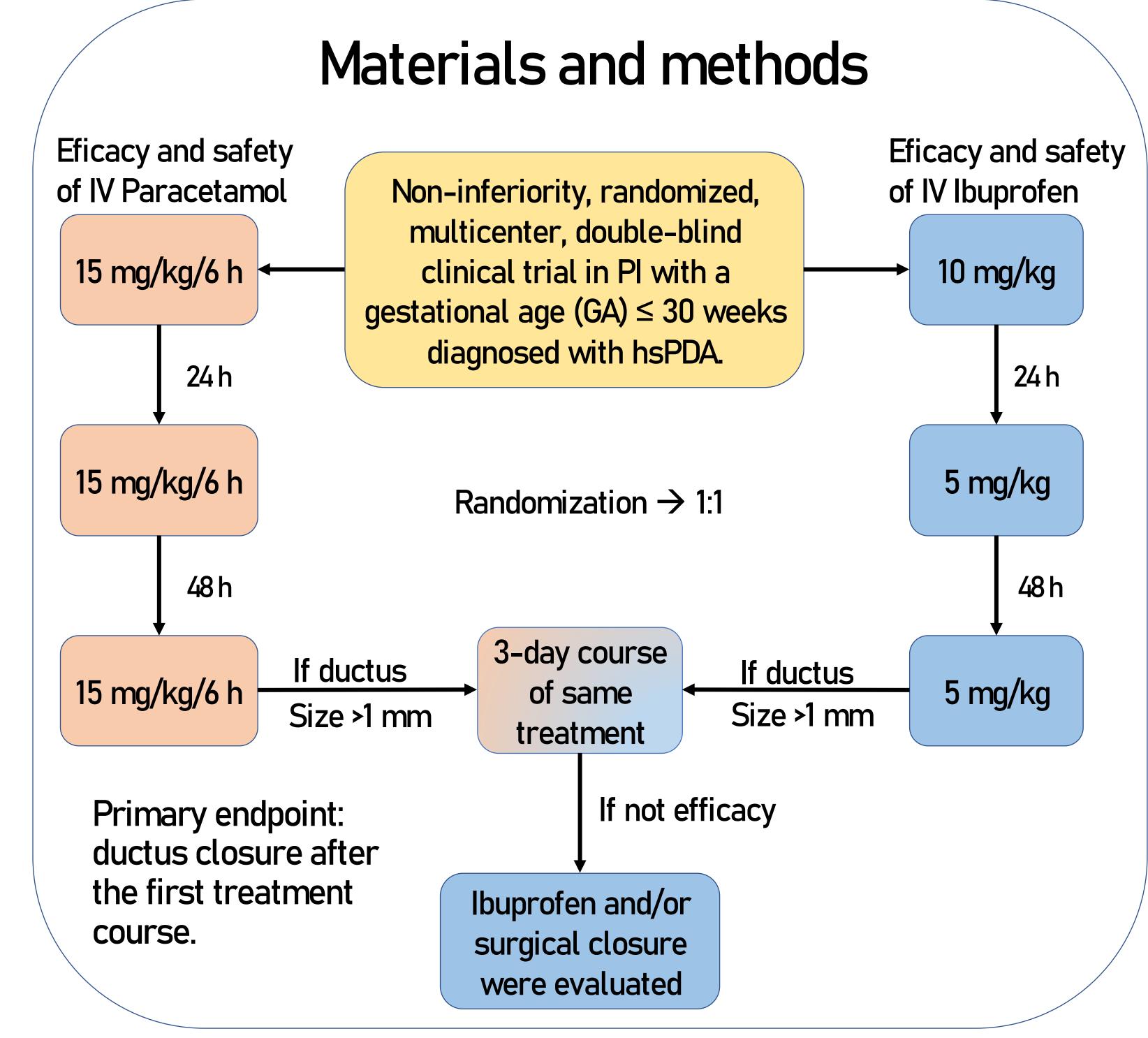
<u>A.A. García Robles¹</u>, Mª.D.M. Serrano Martin², Mª.J. Párraga³, E. Guerrero Hurtado¹, P. Polo Montanero¹, J.L. Poveda Andrés¹, M. Aguar Carrascosa¹, A. Gimeno Navarro¹

¹Hospital Universitario La Fe, Valencia. ²Hospital Regional Universitario Carlos Haya, Málaga. ³Hospital Universitario Reina Sofía, Córdoba.

Background and importance

Hemodynamically significant patent ductus arteriosus (hsPDA) is a common cause of morbidity and mortality in preterm infants (PI), whose treatment of choice is ibuprofen. Paracetamol has been proposed as an alternative, but with insufficient clinical evidence.







Approximately 1/3 of the scheduled recruitment

Adverse events	Treatment A N (%)	Treatment B N (%)	p-value
Renal insufficiency	6 (13,64)	4 (8,51)	0,435
Retinopathy of prematurity	8 (19,05)*	15 (32,61)***	0,15
Bronchopulmonary dysplasia	21 (51,20)**	25 (54,35)***	0,77
Necrotizing enterocolitis	7 (15,91)	5 (10,64)	0,458
Spontaneous intestinal perforation	3 (6,82)	3 (6,38)	0,629
Intraventricular hemorrhage	15 (34,09)	11 (23,4)	0,259
Death	8 (19,05)*	11 (23,4)	0,617
	*Ntotal=42	**Ntotal=41 **	**Ntotal=46

No statistically significant differences 60,004 62,8% Continue or stop the study? Random stop method p = 0,053 The limit for assuming a lack of power. Ductus closure after 1st treatment course Treatment A Treatment B

Conclusions and relevance

It is essential to continue with the planned recruitment. At the moment it is not yet possible to establish a clear recommendation on the use of paracetamol in hsPDA.



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studies - with patient
consent

E-mail address corresponding author: garcia.anarob@gmail.com

