



# A randomised trial of prednisolone *versus* prednisolone and itraconazole in acute-stage allergic bronchopulmonary aspergillosis complicating asthma

Ritesh Agarwal<sup>1</sup>, Valliappan Muthu<sup>1</sup>, Inderpaul Singh Sehgal<sup>1</sup>, Sahajal Dhooria<sup>1</sup>, Kuruswamy Thurai Prasad<sup>1</sup>, Mandeep Garg<sup>2</sup>, Ashutosh Nath Aggarwal<sup>1</sup> and Arunaloke Chakrabarti<sup>3</sup>

<sup>1</sup>Dept of Pulmonary Medicine, Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh, India. <sup>2</sup>Dept of Radiodiagnosis and Imaging, Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh, India. <sup>3</sup>Dept of Medical Microbiology, Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh, India.

Corresponding author: Ritesh Agarwal ([agarwal.ritesh@outlook.in](mailto:agarwal.ritesh@outlook.in))



Shareable abstract (@ERSpublications)

Combination therapy with prednisolone–itraconazole resulted in a nonsignificant decline in the occurrence of ABPA exacerbations at 1 year compared with prednisolone monotherapy in acute-stage ABPA complicating asthma <https://bit.ly/2Yna4Lp>

**Cite this article as:** Agarwal R, Muthu V, Sehgal IS, *et al.* A randomised trial of prednisolone *versus* prednisolone and itraconazole in acute-stage allergic bronchopulmonary aspergillosis complicating asthma. *Eur Respir J* 2022; 59: 2101787 [DOI: 10.1183/13993003.01787-2021].

This single-page version can be shared freely online.

Copyright ©The authors 2022.  
For reproduction rights and  
permissions contact  
[permissions@ersnet.org](mailto:permissions@ersnet.org)

Received: 24 June 2021  
Accepted: 29 Aug 2021

## Abstract

**Background** Whether a combination of glucocorticoid and antifungal triazole is superior to glucocorticoid alone in reducing exacerbations in patients with allergic bronchopulmonary aspergillosis (ABPA) remains unknown. We aimed to compare the efficacy and safety of prednisolone–itraconazole combination *versus* prednisolone monotherapy in ABPA.

**Methods** We randomised subjects with treatment-naïve acute-stage ABPA complicating asthma to receive either prednisolone alone (4 months) or a combination of prednisolone and itraconazole (4 and 6 months, respectively). The primary outcomes were exacerbation rates at 12 months and glucocorticoid-dependent ABPA within 24 months of initiating treatment. The key secondary outcomes were response rates, percentage decline in serum total IgE at 6 weeks, time to first ABPA exacerbation and treatment-emergent adverse events (TEAEs).

**Results** We randomised 191 subjects to receive either prednisolone (n=94) or prednisolone–itraconazole combination (n=97). The 1-year exacerbation rate was 33% and 20.6% in the prednisolone monotherapy and prednisolone–itraconazole combination arms, respectively (p=0.054). None of the participants progressed to glucocorticoid-dependent ABPA. All of the subjects experienced a composite response at 6 weeks, along with a decline in serum total IgE (mean decline 47.6% *versus* 45.5%). The mean time to first ABPA exacerbation (417 days) was not different between the groups. None of the participants required modification of therapy due to TEAEs.

**Conclusions** There was a trend towards a decline in ABPA exacerbations at 1 year with the prednisolone–itraconazole combination *versus* prednisolone monotherapy. A three-arm trial comparing itraconazole and prednisolone monotherapies with their combination, preferably in a multicentric design, is required to define the best treatment strategy for acute-stage ABPA.