

**A randomized controlled trial of the efficacy  
and safety of a fixed triple combination  
(fluocinolone acetonide 0.01%, hydroquinone  
4%, tretinoin 0.05%) compared with  
hydroquinone 4% cream in Asian patients  
with moderate to severe melasma.**

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**摘要**

**Abstract**

**BACKGROUND:** Melasma is an acquired, chronic hypermelanosis for which therapy remains a challenge. **OBJECTIVES:** To compare the efficacy and safety of a triple combination [TC: fluocinolone acetonide 0.01%, hydroquinone (HQ) 4%, tretinoin 0.05%] vs. HQ 4% after 8 weeks of treatment of moderate to severe facial melasma in Asian patients. **METHODS:** This was a multicentre, randomized, controlled, investigator-blinded, parallel comparison study. East and South-East Asian patients aged 18 years or older, with a clinical diagnosis of moderate to severe melasma, were enrolled in this study. Patients were enrolled at baseline and treated daily for 8 weeks with TC cream (one application at bedtime) or HQ cream (twice daily). There were four study visits: at baseline and weeks 2, 4 and 8. The primary efficacy variable was the melasma global severity score (GSS). Other outcome measures included Melasma Area and Severity Index, global improvement and patient satisfaction. Safety was assessed through the reporting of adverse events.

**RESULTS:** TC had superior efficacy to HQ for the primary variable: 77/120 patients (64.2%) on TC had GSS 'none' or 'mild' at week 8 vs. 48/122 patients (39.4%) on HQ ( $P < 0.001$ ). The secondary efficacy variables confirmed these results. Patient satisfaction was in favour of TC (90/127, 70.8%, vs. 64/129, 49.6%;  $P = 0.005$ ). More patients had related adverse events on TC (63/129, 48.8%) than on HQ (18/131, 13.7%) but most were mild and none was severe. **CONCLUSIONS:** Efficacy in Asians and patient satisfaction were

superior with the fixed TC than with HQ 4%.