Clofazimine for the treatment of multidrug-resistant tuberculosis: prospective, multicenter, randomized controlled study in China
Shenjie Tang, Lan Yao, Xiaohui Hao, Yidian Liu, Linhai Zeng, Gang Liu, Mingwu Li, Fujian Li, Meiyong Wu, Yousheng Zhu, Hua Sun, Jin Gu, Xiafang Wang, and Zhanjun Zhang

Background

As MDR-TB treatment programs mature and as successful outcomes average 48%, the reality is that many of our patients will require re-treatment. Not only XDR patients but lost-to-follow-up, poorly compliant patients and contacts of XDR-TB patients become increasingly frequent. We are of course waiting for new drugs and regimens, but in many settings this does not help the patients who are sick right now. Re-treatment DR patients require at least 2 new drugs to give the best chance of cure usually involving the use of group 5 drugs. However, it is increasingly clear that not all group 5 drugs are created equal. Programs must decide whether they can invest in group 5 drugs and how best to use them.

Clofazimine was designed as a TB drug but initial studies were disappointing. It was subsequently licensed for use in multibacillary leprosy and was then protected due to limited treatment options in this setting. After brief forays as a treatment for inflammatory bowel disease, it has come full circle and is now back in use as drug for MDR-TB. To date, its utility has been controversial with significant heterogeneity amongst observational cohorts and varied conclusions from meta-analyses by Gopal and Dey. It is not yet recommended as a first line drug by the WHO. However, with mounting evidence that the so-called “Bangladesh” 9-11 month regimen might be effective in some settings, it is postulated that clofazimine might be the key.

This is the first published randomised, controlled trial examining clofazimine added to a 21-month background WHO recommended regimen.

Questions to think about

- Have you used clofazimine? If so, in what circumstances and what other drugs do you use in combination?
- How big a problem is skin pigmentation in your setting? Does it contribute significantly to stigma (perceived or real)?
- Do you perceive clofazimine is responsible for other side effects?
- Are you surprised by the findings in this study? Does this study change your approach to regimen construction? Do you think it is worth considering in first line MDR regimens?