

primary studies - published RCT

Tobramycin inhalation powder manufactured by improved process in cystic fibrosis: the randomized EDIT trial.

Code: PM23672633 **Year:** 2013 **Date:** 2017

Author: Galeva I

Study design (if review, criteria of inclusion for studies)

Non-blinded randomised controlled trial

Participants

45 clinically stable cystic fibrosis patients (44% female, 4-45 years, mean age 11.5 years) with newly positive methicillin resistant *Staphylococcus aureus* (MRSA) cultures.

Interventions

a non-blinded eradication protocol (Rx) compared with observation (Obs). The Rx protocol was: oral trimethoprim-sulfamethoxazole or if sulfa-allergic, minocycline plus oral rifampin; chlorhexidine mouthwash for 2 weeks; nasal mupirocin and chlorhexidine body wipes for 5 days and environmental decontamination for 21 days.

Outcome measures

The primary end point was MRSA culture status at day 28.

Main results

Between 1 April 2011 to September 2014, 45 participants (44% female, mean age 11.5 years) were randomised (24 Rx, 21 Obs). At day 28, 82% (n=18/22) of participants in the Rx arm compared with 26% (n=5/19) in the Obs arm were MRSA-negative. Adjusted for interim monitoring, this difference was 52% (95% CI 23% to 80%, p

Authors' conclusions

This MRSA eradication protocol for newly acquired MRSA demonstrated microbiological efficacy with a large treatment effect.

<http://dx.doi.org/10.1185/03007995.2013.805122>

See also

Curr Med Res Opin. 2013 May 14.

Keywords

Anti-Bacterial Agents; Bacterial Infections; Infection; Minocycline; Mupirocin; pharmacological_intervention; Respiratory Tract Diseases; Respiratory Tract Infections; Rifampin; *Staphylococcus aureus*; Cotrimoxazole; Oral; Sulfonamides; other anti-bacterial agents; Tetracyclines;