

primary studies - published RCT

# Treatment of low bone density in young people with cystic fibrosis: a multicentre, prospective, open-label observational study of calcium and calcifediol followed by a randomised placebo-controlled trial of alendronate

Code: PM24429202

Year: 2013 Date: 2017

Author: Bianchi ML

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

Real-world, open-label, crossover, interventional phase IV study

## Participants

CF patients aged  $\geq 6$  years with forced expiratory volume in 1 second (FEV1)  $\geq 25\%$  to

## Interventions

Patients were assigned to one of the three treatment arms in Cycle 1; all patients received TIP in Cycle 2. Each cycle consisted of 28 days on and 28 days off the treatment.

## Outcome measures

Total administration time, which included device setup and cleaning, patients with contaminated devices, treatment satisfaction, assessed by the Treatment Satisfaction Questionnaire for Medication and ACCEPT questionnaire, adverse events.

## Main results

A total of 60 patients [mean (standard deviation) age, 27.6 (8.4) years] were allocated to three treatment arms [TIS/TIP (n = 14); COLI/TIP (n = 28); TIP/TIP (n = 18)] in Cycle 1. The mean total administration time, which included device setup and cleaning, in Cycle 1 versus Cycle 2 for TIS/TIP, COLI/TIP, and TIP/TIP arms were 37.0 versus 5.0 min, 16.4 versus 3.8 min, and 4.2 versus 3.4 min, respectively. The difference in mean total administration time was significantly shorter in Cycle 2 than in Cycle 1 for TIS/TIP ( $p = 0.0112$ ) and COLI/TIP ( $p = 0.0016$ ) arms. Overall, 12 patients were found to have contaminated devices across the two treatment cycles. In the TIP/TIP arm, no contamination of the T-326 inhaler was observed in either cycle. Treatment satisfaction, assessed by the Treatment Satisfaction Questionnaire for Medication and ACCEPT questionnaire, was better overall for TIP compared with TIS and COLI. There were no unexpected adverse events and most were mild or moderate in intensity.

## Authors' conclusions

The T-326 inhaler used to deliver TIP was easy to use, required shorter total administration time, and was much less frequently contaminated than the nebulizers. The safety findings observed for TIP were generally consistent with its established safety profile.

[http://dx.doi.org/10.1016/S2213-2600\(13\)70064-X](http://dx.doi.org/10.1016/S2213-2600(13)70064-X)

## See also

Lancet Respir Med. 2013 Jul;1(5):377-85. doi: 10.1016/S2213-2600(13)70064-X. Epub 2013 Jun 2.

## Keywords

Anti-Bacterial Agents; Bacterial Infections; Infection; Inhalation OR nebulised; nebuliser; pharmacological\_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Colistin; Tobramycin; Exacerbation; Aminoglycosides; other anti-bacterial agents; colistimethate; Powders; Child; Adolescent; Adult;