

Author	Current study	Villarino et al ³	Cruz and Stark ⁸	Cruz and Stark ⁷
<u>Study Design</u>				
Study Period	2017 - 2019	2001 - 2013	2014 - 2015	2014 - 2017
Sample Size	22	1058	80	667
Type of Study	Retrospective Chart Review	Parallel Design Unrestricted Randomization Method	Retrospective cohort study	Nonrandomized retrospective cohort study
Treatment Group	3HP with DOT	3HP with DOT	3HP with DOT	3HP with DOT
Control Group	None	9H therapy without DOT	None	9H and 4R therapy without DOT
<u>Race/Ethnicity</u>				
White	32%	5%	1%	11%
Black	32%	11%	25%	18%
Asian	32%	10%	13%	21%
Hispanic/Latino	4%	74%	61%	50%
<u>Age</u>				
Age Range (years)	2 to 20	2 to 17	0 to 21	0 to 18
Median age (years)	12.5	10	13.5	11.2 y.o (3HP) versus 4.5 y.o (9H/ 3R)
<u>Adverse Event Rate in 3HP Therapy</u>				

Grade 1+2	11 (50%)	11 (2%)	Only reported total ADR was 5 subjects (6%)	Grade 1 = 24 (8.5%) Grade 2 = 0
Grade 3	2 (9%)	3 (0.6%)	Not reported	0
Grade 4	0	0	Not reported	0
<u>Adverse Event Rate in Control</u>				
Grades 1+2	Not applicable	5 (1%)	Not applicable	9H: Grade 1: 27 (11.5%) Grade 2: 4 (1.7%) 4R: Grade 1:6 (4.8%) Grade 2: 0
Grade 3	Not applicable	1 (0.2%)	Not applicable	9H: 4 (1.7%) 4R:
Grade 4	Not applicable	0	Not applicable	9H: 1 (0.4%) 4R: 0
Treatment Discontinuation due to ADRs in 3HP	9%	1.7%	6%	1.4%
Treatment Discontinuation due to ADRs in	Not applicable	0.5%	Not applicable	2.8% (9H) 0.75% (4R)

control				
Notes		Cited by CDC in 2017 Report	Completion was defined as at least 11 doses over a 16 week period	7 other subjects terminated treatment (did not specify whether from 3HP or 9H)

Table 1. Short course combination regimen of weekly isoniazid and rifapentine (3HP); Directly observed

therapy (DOT); 9 months of daily isoniazid (9H).