The PREVENT TB Study
TB Trials Consortium Study 26

3 months of once-weekly rifapentine plus INH vs. 9 months of daily INH for treatment of latent TB infection

•Sterling TR, Villarino ME, Borisov AS, Shang N, Gordin F, Bliven-Sizemore E, Hackman J, Hamilton CD, Menzies D, Kerrigan A, Weis SE, Weiner M, Wing D, Conde MB, Bozeman L, Horsburgh Jr. CR, Chaisson RE, and the TB Trials Consortium of the Centers for Disease Control and Prevention

Background

- Treatment of latent *M. tuberculosis* infection is a key component of TB prevention and elimination

- 9 months of isoniazid (INH) is highly efficacious, but effectiveness is diminished by low completion rates (30-60%)

- A shorter regimen is needed
  - High completion rates, effectiveness, and tolerability

Study Design

Once-weekly, directly-observed rifapentine + INH x 3 months
(3HP)
vs.
Daily, self-administered INH x 9 months
(9H)

For the treatment of latent TB infection in
high-risk tuberculin skin-test reactors

Randomized, open-label
33 months of follow-up from date of enrollment

Study Doses

- Rifapentine + INH x 3 months (3HP): 12 doses
  - Rifapentine 900 mg
    - Graduated dosing for persons ≤ 50 kg
  - Isoniazid 15-25 mg/kg; 900 mg max.

- Isoniazid x 9 months (9H): 270 doses
  - Isoniazid 5-15 mg/kg; 300 mg max.

- Vitamin B6 (pyridoxine) 50 mg with each INH dose

Inclusion Criteria

- Persons > 2 years old who were:
  - Tuberculin skin-test (TST)-positive close contacts of a culture-confirmed TB case
  - TST-converters
    - Documented negative → positive within 2 years
  - HIV-infected with
    - Positive TST
    - Close contact to TB case regardless of TST
  - TST-positive, fibrosis on chest radiograph consistent with prior untreated TB
  - Children 2-4 years old with + TST or close contact with a culture-confirmed TB case

Exclusion Criteria

- Confirmed or suspected TB
- TB resistant to INH or rifampin in source case
- History of treatment with
  - > 14 consecutive days with a rifamycin
  - > 30 days with INH
- Prior treatment of TB or *M. tuberculosis* infection in HIV-uninfected persons
- Intolerance to INH or rifamycins
- Aspartate aminotransferase (AST) > 5x upper limit if AST determined
- Pregnant or lactating females
- HIV-1 antiretroviral therapy within 90 days of enrollment
- Weight < 10 kg

Primary Aim

- Evaluate the effectiveness of weekly 3HP vs. daily 9H

- Primary endpoint:
  - Culture-confirmed TB in persons ≥ 18 y.o and culture-confirmed or clinical TB in persons < 18 y.o.

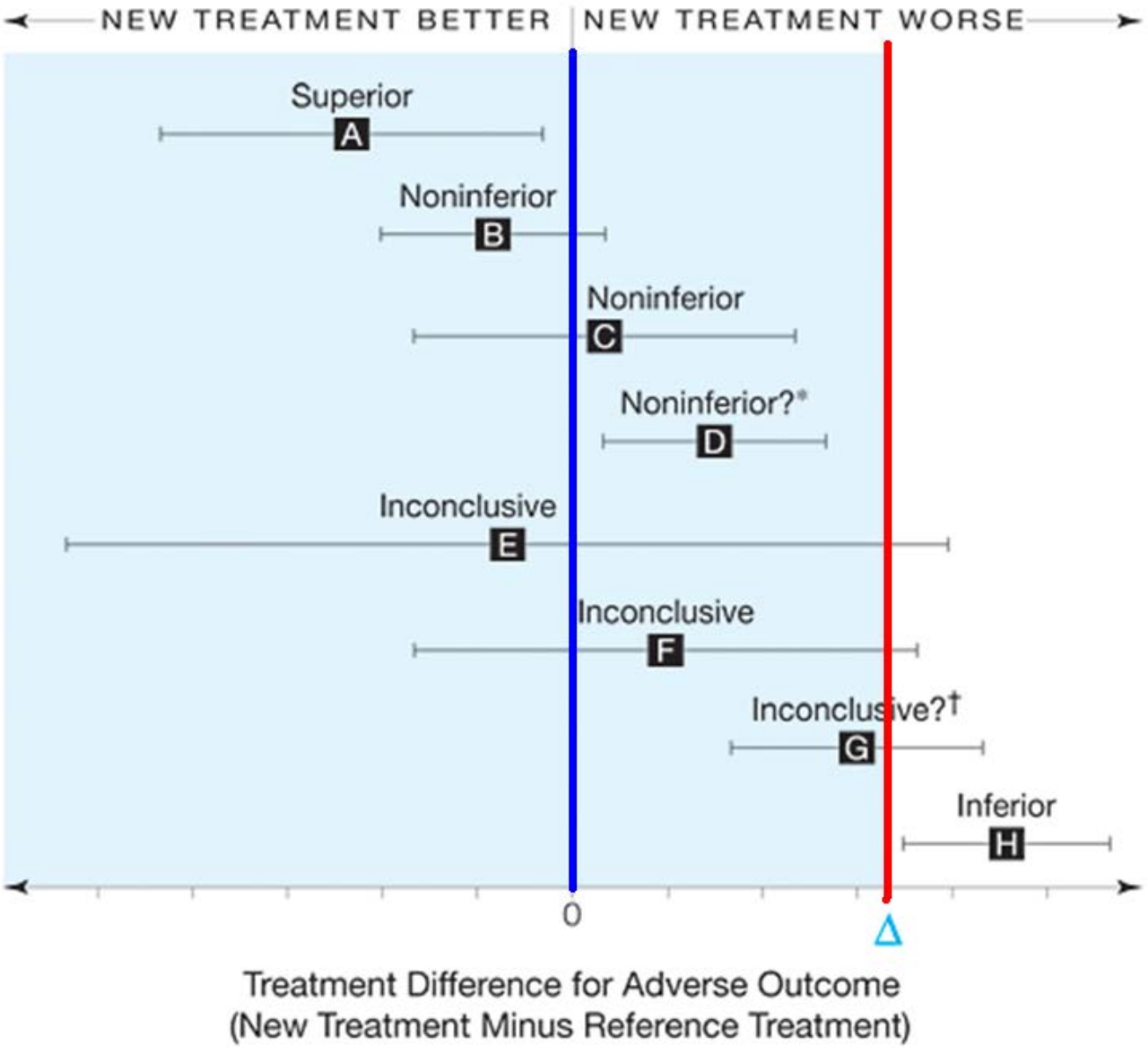
Secondary Aims

- Evaluate the tolerability of weekly 3HP vs. daily 9H
- Secondary endpoints:
  - Treatment completion
  - Permanent drug discontinuation for any reason
  - Drug discontinuation due to adverse drug reaction
  - Grade 3, 4, and 5 toxicity
  - Culture-confirmed or clinical TB in all persons
  - Resistance to study medications among persons developing TB

Study Design and Sample Size

- Non-inferiority study design
  - Non-inferiority margin (delta): 0.75%
- > 80% power to demonstrate that 3HP is not inferior to 9H
  - 3,200 persons per arm
- Allow for 20% loss
  - Loss to follow-up
  - Clustering of enrollments
- 4,000 persons per arm

Possible Scenarios of Observed Treatment Differences in Noninferiority Trials



Piaggio, G. et al. JAMA 2006;295:1152-1160.

Enrollment

- Enrollment began June 2001
- Enrollment ended February 15, 2008
- Follow-up ended September 30, 2010

Analysis Populations

- Enrolled before February 15, 2008
  - Completed 33 months of follow-up by September 30, 2010
- Intention-to-treat (ITT)
  - All persons enrolled in the study
- Modified intention-to-treat (MITT)
  - Enrolled in the study
  - Eligible
- Per protocol (PP)
  - All persons enrolled in the study who were eligible
  - Completed study drug within targeted time period
  - Or developed TB or died but completed $\geq$ 75% of expected doses prior to event
  - All follow-up time counted; did not require reaching 33 months

Effectiveness and Efficacy

- Effectiveness:
  - TB rate among all persons enrolled who were eligible for the study
    - MITT
    - Takes into account nonadherence
- Efficacy
  - TB rate among all persons who were enrolled, eligible, and completed therapy
    - PP
    - Best-case scenario regarding drug activity

Analysis Populations

- In group settings (e.g., households), participants could be placed on the same regimen as the first person in the group (cluster)
  - Only the first person in that cluster was randomized
  - The size of clusters varied by arm early in the study
  - Later, entire cluster had to be identified before randomization of first person
- For MITT and PP populations, we therefore assessed results for:
  - All patients enrolled
  - First patient enrolled in a cluster

Analysis Populations

- Enrolled (ITT) 8,053
- Eligible (MITT) 7,731
  - 9H 3,745
  - 3HP 3,986
- Per protocol (PP) 5,858
  - 9H 2,585
  - 3HP 3,273

Reason for Ineligibility
N=322 (of 8,053)

Reason	**Frequency**	**%**
Source TB case resistant to INH or RIF	161	50
Source TB case culture-negative for *M. tuberculosis*	103	32
Positive TST not confirmed	37	12
No susceptibility testing for index case	14	4
TB at enrollment	7	2
Total	322	100%

Clinical and Demographic Characteristics

MITT Population

Characteristic	**9H** **N=**3,745	**3HP** **N=**3,986
Age (median, IQR)	36 (25-46)	37 (25-47)
Male sex	2,004 (54)	2,210 (55)
Race		
White	2,160 (58)	2,296 (58)
Black	947 (25)	978 (25)
Asian/Pac. Island	490 (13)	494 (12)
Am./Can. Indian	33 (1)	84 (2)*
Multiracial (Brazil)	115 (3)	134 (3)
Ethnicity (US/Can)		
Hispanic	1,442 (43)	1,576 (44)
Non-Hispanic	1,899 (57)	1,966 (56)

Clinical and Demographic Characteristics

MITT Population

Characteristic	**9H** **N=**3,745	**3HP** **N=**3,986
HIV-infected	100 (3)	105 (3)
BMI (median, IQR)	27 (23-30)	27 (23-31)
Site of recruitment		
U.S./Canada	3,341 (89)	3,542 (89)
Brazil/Spain	404 (11)	444 (11)
Completed high school	2,126 (57)	2,269 (57)
Jail/prison ever	175 (5)	221 (6)
Unemployed	390 (10)	424 (11)
Hx EtOH at enrollment	1,888 (50)	1,929 (48)
Hx IDU at enrollment	136 (4)	149 (4)
Current tobacco	1,034 (28)	1,112 (28)

Clinical and Demographic Characteristics

MITT Population

Characteristic	**9H** **N=**3,745	**3HP** **N=**3,986
Indication for TLI		
Close contact	2,609 (70)	2,857 (72)
Recent TST converter	972 (26)	953 (24)
HIV-infected	74 (2)	87 (2)
Fibrosis on CXR	90 (2)	89 (2)
Co-morbid liver disease		
HCV	97 (3)	99 (3)
HBV	60 (2)	42 (1)

Follow-up and Retention

Measure	9H	3HP
Person-years of follow-up	9,619	10,327
# months in study (mean)	30.3	30.7
Proportion of participants completing month 33 follow-up visit	86%	88%

Event rate estimates and the non-inferiority test for A33

33 months of follow-up from time of randomization

Population	study arms	# of patients	# TB cases	TB per 100 p-y	Cumulative TB rate (%)	Difference in cumulative TB rate	Upper bound of 95% CI of difference in cumulative TB rates*
MITT	9H	3,745	15	0.16	0.43	-0.24	0.01
	3HP	3,986	7	0.07	0.19		
Per Protocol	9H	2,585	8	0.11	0.32	-0.19	0.06
	3HP	3,273	4	0.05	0.13		

* non-inferiority margin (delta) = 0.75%

Difference in TB rates between the 2 study arms, and non-inferiority “delta”

Modified Intention to Treat Population; A33 analysis

Difference in TB rates between the 2 study arms, and non-inferiority “delta”

<u>Per Protocol Population</u>; A33 analysis

Cumulative TB Rate

33 months from enrollment—MITT

Log-rank P-value: 0.06

Additional Analyses

- 24 months from completion of treatment
  - Similar results
- Limited to first person enrolled in cluster
  - Similar results
- Including 4 culture-negative TB cases in adults (total TB = 26) (secondary endpoint)
  - Similar results
- Sensitivity analysis of primary endpoint
  - Number of additional cases in 3HP arm required to be unable to claim non-inferiority (assuming no additional cases in 9H arm):
    - 23

Tolerability
Participants who took ≥1 dose

Outcome	**9H** **N=3,759**	**3HP** **N=4,040**	**P-value**
Treatment completion	2,599 (69.0%)	3,327 (82.0%)	< 0.0001
Permanent drug d/c-any reason	1,160 (31.0%)	713 (18.0%)	< 0.0001
Permanent drug d/c-due to an adverse event	139 (3.7%)	196 (4.9%)	0.009
Death	39 (1.0%)	31 (0.8%)	0.22

Reported Adverse Events

Among persons receiving ≥ 1 dose
During treatment or within 60 days of the last dose
Regardless of attribution to study drug

Toxicity	9H N=3,759	3HP N=4,040	P-value
Grade 1-2	341 (9.0%)	310 (7.6%)	0.03
Grade 3	203 (5.4%)	193 (4.8%)	0.22
Grade 4	43 (1.1%)	36 (0.9%)	0.27

Reported Adverse Events

Among persons receiving ≥ 1 dose
During treatment or within 60 days of the last dose
Accounting for attribution to study drug

Toxicity	9H N=3,759	3HP N=4,040	P-value
Related to drug	206 (5.5)	328 (8.1)	<0.0001
Rash only	17 (0.5)	35 (0.9)	0.02
Possible HS	15 (0.4)	158 (3.9)	<0.0001
Other	71 (2.0)	122 (3.0)	0.001
Not related	399 (10.3)	220 (5.5)	<0.0001

HS: hypersensitivity reaction

Hepatotoxicity

Among persons receiving ≥ 1 dose
During treatment or within 60 days of the last dose

Toxicity	9H N=3,759	3HP N=4,040	P-value
All hepatotoxicity	113 (3.0)	24 (0.6)	<0.0001
Related to drug	103 (2.7)	18 (0.5)	<0.0001
Not related	13 (0.4)	6 (0.2)	0.08

Possible Hypersensitivity

Among persons receiving ≥ 1 dose
During treatment or within 60 days of the last dose

Toxicity	9H N=3,759	3HP N=4,040	P-value
All hypersensitivity reactions	17 (0.5)	152 (3.8)	<0.0001
HS reactions with treatment discontinuation	15 (0.4)	117 (2.9)	<0.0001
HS reactions w/ hypotension*	0	6 (0.15)	

Systolic BP <90 mm Hg G1 n=3, G2 n=1, G3 n=2

Risk Factor Analysis-for TB

Univariate

Characteristic	Reference group	HR (95% CI)	P-value
Regimen (3RPT/INH)	9INH	0.43 (0.18, 1.07)	0.07
Age (10 years)	10 years younger	0.87 (0.65, 1.17)	0.37
Male sex	Female	1.50 (0.63, 3.58)	0.35
Black race	White race	1.56 (0.64, 3.81)	0.33
HIV +	HIV negative	7.00 (2.19, 22.30)	0.001
BMI (1 unit)	1 unit lower	0.85 (0.78, 0.93)	0.0006
EtOH abuse	No EtOH	4.84 (1.58, 14.78)	0.006
Current smoking	No smoking	4.73 (1.98, 11.27)	0.0005
IDU	No IDU	1.29 (0.17, 9.59)	0.80
High school	Completed	1.21 (0.51, 2.85)	0.66
Jail/prison	No jail/prison	3.12 (0.92, 10.54)	0.07
Unemployed	Not unemployed	2.55 (0.94, 6.92)	0.07

No interaction between treatment arm and above variables.

Risk Factor Analysis-for TB

Multivariate

Characteristic	Reference group	HR (95% CI)	P-value
Regimen (3RPT/INH)	9INH	0.38 (0.15, 0.99)	0.05
Age (10 years)	10 years younger		
Male sex	Female		
Black race	White race		
HIV +	HIV neg/unknown	4.07 (1.26, 3.16)	0.01
BMI (1 unit)	1 unit lower	0.81 (0.73, 0.90)	0.0002
EtOH abuse	EtOH use or none		
Smoking-current	Smoke last 5 yrs/never	4.89 (1.90, 12.58)	0.001
IDU	No IDU		
High school	Completed		
Jail/prison	No jail/prison		
Unemployed	Not unemployed		

Drug Resistance
Among TB cases

	9H N=12	3HP N=7
INH resistant	2	0
Rifampin resistant	0	1*

* *M. bovis* in an HIV-infected person who completed therapy late due to treatment interruptions

Causes of Death by Arm

Category	Arm A (N/%)	Arm B (N/%)
Malignant neoplasms (cancer)	15/38.46	8/25.81
Intentional injuries	6/15.38	1/3.23
Diseases of heart	4/10.26	8/25.81
Unintentional injuries	3/7.69	3/9.68
Chronic liver disease or cirrhosis	2/5.13	4/12.9
Hypertension (with or w/o renal disease)	2/5.13	1/3.23
AIDS	1/2.56	1/3.23
Cerebrovascular diseases	1/2.56	4/12.9
Chronic lower respiratory diseases	1/2.56	0/0
Chronic pancreatitis	1/2.56	0/0
Diabetes mellitus	1/2.56	0/0
Septicemia	1/2.56	1/3.23
Unknown	1/2.56	0/0
Total	***39***	***31***

Limitations

- Few HIV-infected participants
  - Enrollment of this population was extended to December 2010
  - Tolerability and effectiveness data pending
- Complete tolerability assessment in young children also pending
  - Enrollment of children 2-11 years old extended to December 2010

Conclusions

The PREVENT TB Study
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- **The effectiveness of 3HP was not inferior to 9H**
  - **3HP was at least as effective as 9H**
    - **The 3HP TB rate was approximately half that of 9H**
- **The 3HP completion rate was significantly higher than 9H**
  - **82% vs. 69%**
- **3HP was safe relative to 9H**
  - **Lower rates of:**
    - **Any adverse event**
    - **Hepatotoxicity attributable to study drug**

Conclusions

The PREVENT TB Study
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- **Permanent drug discontinuation due to adverse event was higher in 3HP**
  - **4.7% vs. 3.6%**
- **Rates of any adverse event attributable to study drug also higher in 3HP**
  - **8.1% vs. 5.5%**
  - **This relationship also seen with rash, possible hypersensitivity**
- **Rates of grade 3 and 4 toxicity did not differ by arm**
- **Rates of death low (~ 1%) in both arms**

Interpretation

- The higher rates of 3HP drug discontinuation due to an adverse event and adverse event attributable to study drug could be related to:
  - Worse tolerability of 3HP
  - More frequent interaction with study personnel
    - Weekly in 3HP vs. monthly in 9H
  - Open-label design with novel regimen
    - participants and investigators

Potential Impact on TB Control

- 3HP is an alternative to 9H for treatment of latent *M. tuberculosis* infection in persons at high-risk for progression to TB
- Higher completion rates for treatment of LTBI
- 3HP as effective as 9H in this clinical trial
  - 3HP could be more effective than 9H in operational settings, particularly if 3HP is given under direct observation and 9H completion rates are 30-60%
  - Greater effectiveness → more TB prevented

Dissemination of Results
Uptake of Regimen

- CDC recommendation/guidelines
  - After publication of paper
- ATS/CDC/IDSA guidelines
  - Process starting now
  - May require >2 years to finalize
- Availability of rifapentine
- Ability of TB programs to implement DOT
- Monitoring for adverse events
  - Past history of isoniazid, rifampin + pyrazinamide

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