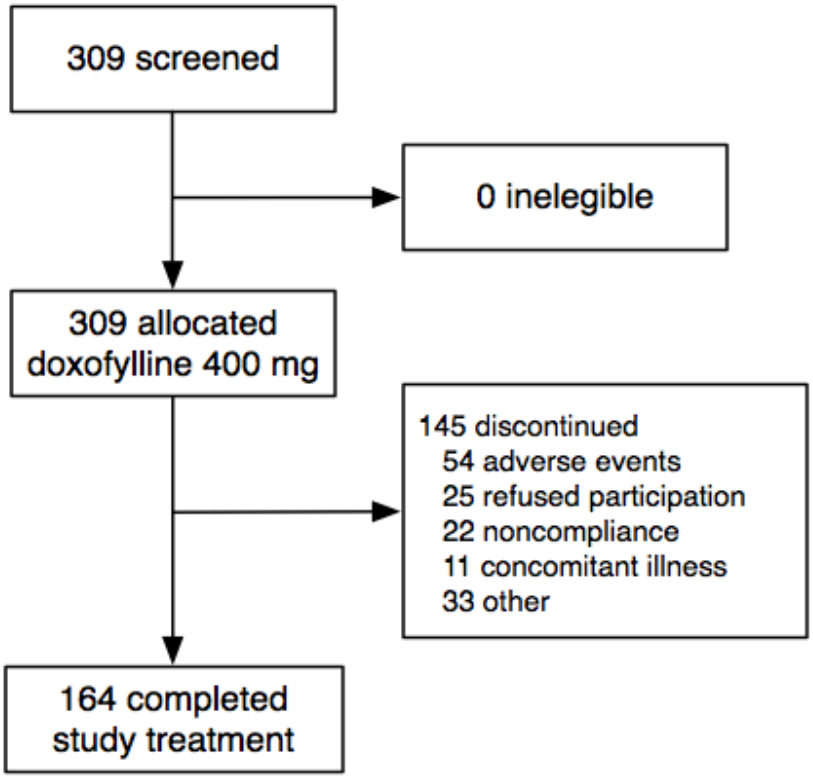
Participant flow



Baseline characteristics

Summary of demographic and baseline data (intent-to treat subjects)

	Doxofylline 400 mg
Number of subjects	309
Age (yr)	
Mean (SEM)	38.2 (0.7)
Sex	
Male	136 (44.0%)
Female	173 (56.0%)
Race	
Caucasian	251 (81.2%)
Black	37 (12.0%)
Hispanic	18 (5.8%)
Other	3 (1.0%)
Body weight (kg)	
Mean (SEM)	81.35 (1.08)
Height (cm)	
Mean (SEM)	167.66 (0.63)
% of predicted FEV_1	
Mean (SEM)	65.4 (0.5)
No. of asthma events/day	
Mean (SEM)	1.87 (0.16)
Albuterol use (puffs/day)	
Mean (SEM)	3.61 (0.33)
Precipitating factors	
Yes	297 (96.1%)
No	12 (3.9%)
Hospitalizations for asthma	
Yes	131 (42.8%)
No	178 (57.6%)
Age at onset of asthma (yr)	
Mean (SEM)	18.70 (1.00)
Years since onset	
Mean (SEM)	19.50 (0.70)

SEM = standard error of mean

Outcome measures

Primary efficacy outcome: percent Increases in FEV_1 at primary endpoint[a] (change from baseline in the value recorded 2 h after dose administration).

Treatment	n	Mean (SEM)
Doxofylline 400 mg	228	16.20 (1.70)***

***P<0.001 vs. baseline (t-test analysis).
[a] Combined results from each subject's last visit during the active-treatment period, regardless of when it occurred.

Secondary efficacy outcome: percent increases in FEV_1 induced by doxofylline 400 mg during the study at different time-points (change from baseline in the value recorded 2 h after dose administration).

Months	n	Mean (SEM)
1	227	14.63 (1.54)***
3	199	18.10 (1.66)***
6	182	20.69 (2.07)***
9	173	15.46 (1.93)***
12	164	15.60 (1.87)***

***P<0.001 vs. baseline (t-test analysis).

Secondary efficacy outcome: asthma events rate (n of events/day) during the study at different time-points.

Months	n	Mean (SEM)
1	269	1.61 (0.11)
2	217	1.48 (0.13)*
3	203	1.46 (0.13)*
4	197	1.44 (0.14)*
5	195	1.47 (0.15)*
6	188	1.45 (0.21)
7	182	1.18 (0.12)**
8	177	1.21 (0.12)**
9	176	1.19 (0.12)**
10	174	1.14 (0.12)**
11	170	1.18 (0.14) **
12	168	1.30 (0.18)*

*<0.05, **P<0.01 vs. baseline (t-test analysis).

Secondary efficacy outcome: albuterol use rate (n of puffs/day) during the study at different time-points.

Months	n	Mean (SEM)
1	269	2.79 (0.20)*
2	216	2.71 (0.24)*
3	203	2.59 (0.23)*
4	197	2.51 (0.24)**
5	195	2.57 (0.24)*
6	188	2.52 (0.46)*
7	182	2.12 (0.22)***
8	177	2.20 (0.22)**
9	176	2.27 (0.25)**
10	174	2.09 (0.22)***
11	170	2.06 (0.22)***
12	168	2.13 (0.25)**

*<0.05, **P<0.01, ***P<0.001 vs. baseline (t-test analysis).

Secondary safety outcome: summary of most common adverse events (n and %). No subjects died during or shortly after finishing the study. No subjects experienced serious adverse events.

	Doxofylline 400 mg (n=309)
Subjects with one or more adverse event	169 (54.69)
Body as a whole disorders	
Asthenia	12 (3.88)
Headache	44 (14.24)
Infection	7 (2.27)
Abdominal pain	13 (4.21)
Chest pain	8 (2.59)
Digestive disorders	
Anorexia	7 (2.27)
Diarrhoea	8 (2.59)
Dyspepsia	31 (10.03)
Nausea	45 (14.56)
Nervous system disorders	
Dizziness	11 (3.56)
Insomnia	33 (10.68)
Nervousness	20 (6.47)
Respiratory system disorders	
Asthma	23 (7.44)
Pharyngitis	10 (3.24)

Adverse Events

Secondary safety outcome: summary of most common adverse events (n and %). No subjects died during or shortly after finishing the study. No subjects experienced serious adverse events.

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