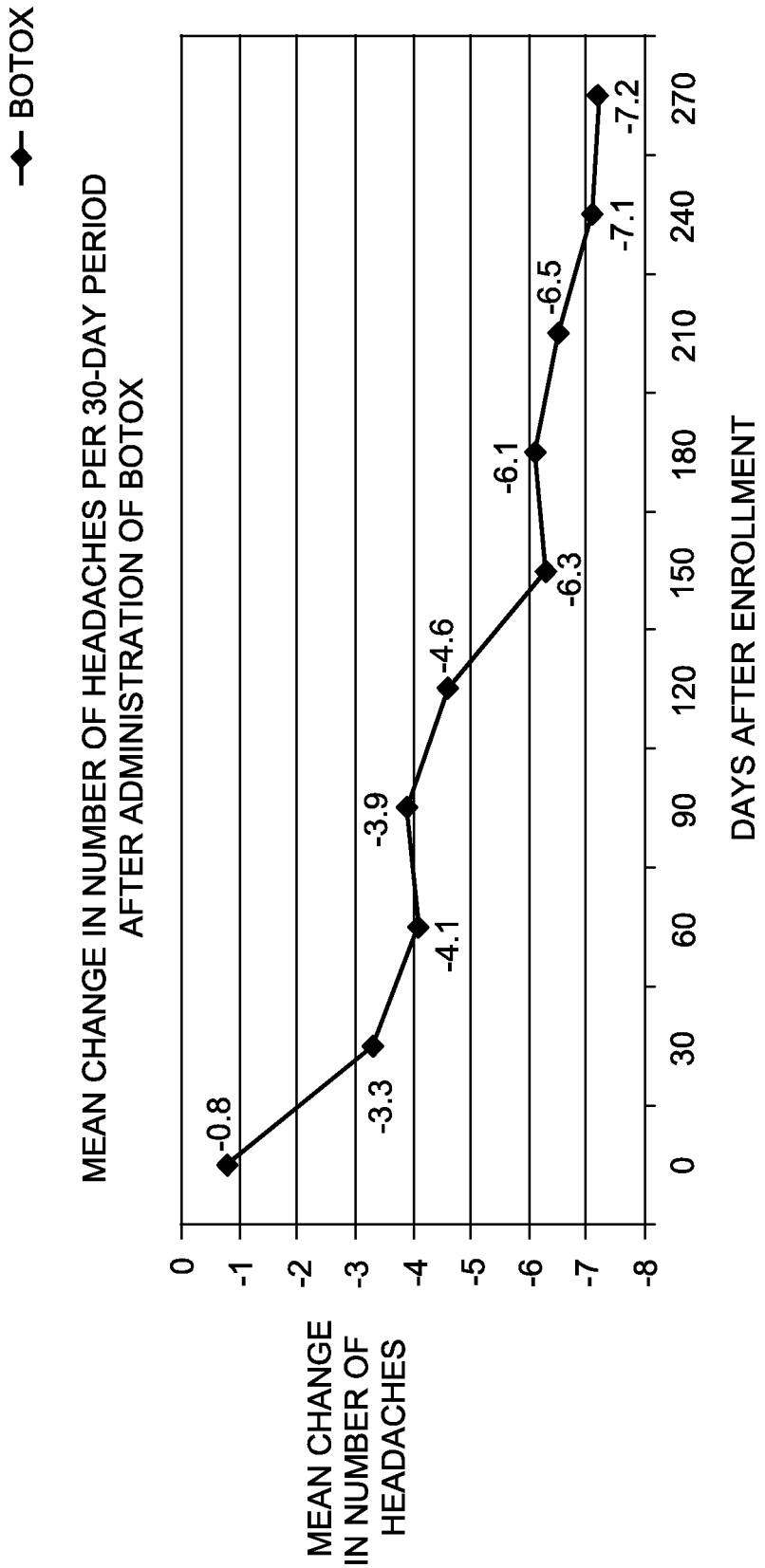

BOTOX
MEAN CHANGE IN NUMBER OF HEADACHES PER 30-DAY PERIOD AFTER ADMINISTRATION OF BOTOX
MEAN CHANGE IN NUMBER OF HEADACHES
0
-1
-2
-3
-4
-5
-6
-7
-8
0
30
60
90
120
150
180
210
240
270
DAYS AFTER ENROLLMENT
-0.8
-3.3
-4.1
-3.9
-4.6
-6.3
-6.1
-6.5
-7.1
-7.2

FIG. 1

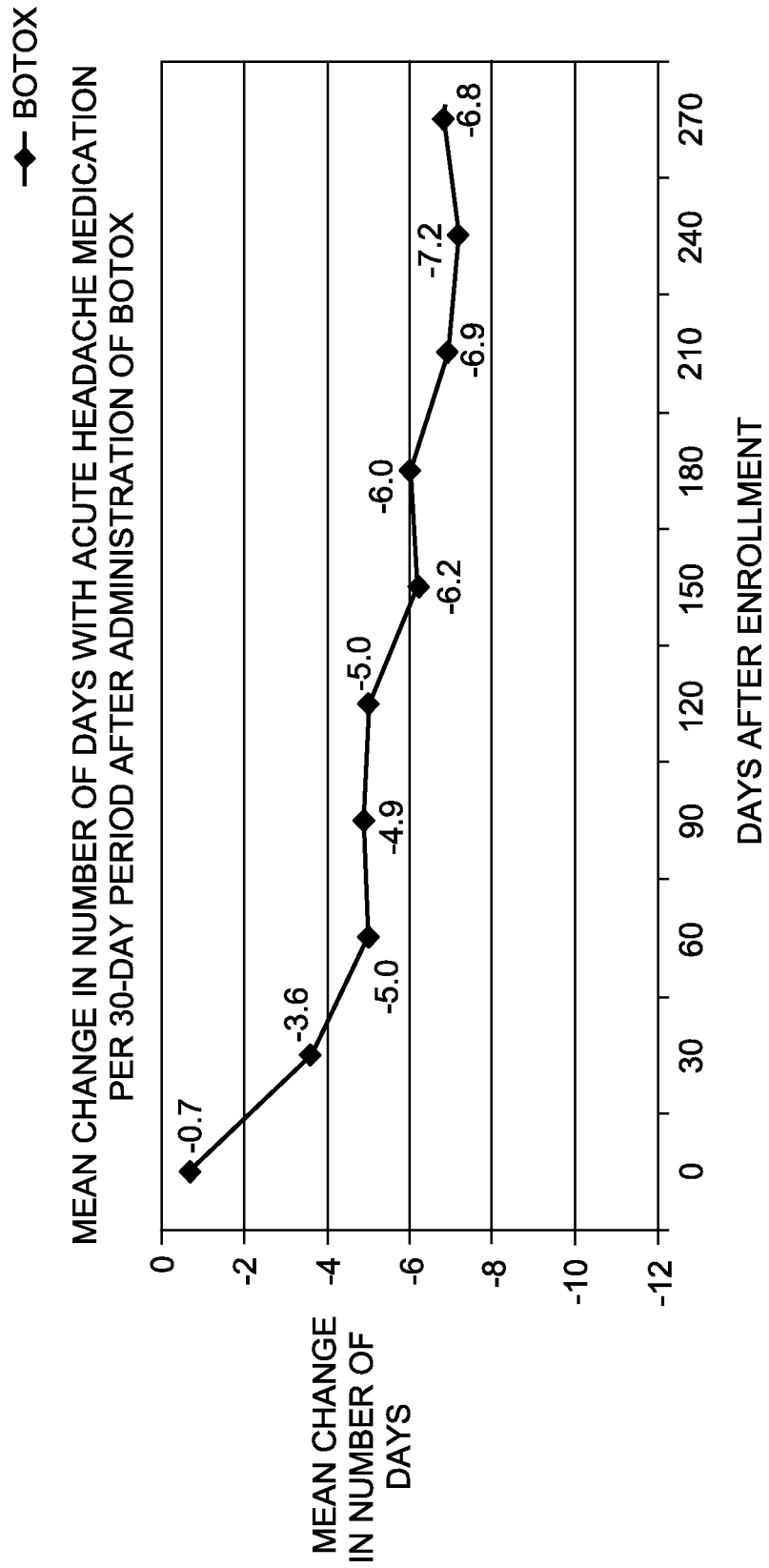

BOTOX
MEAN CHANGE IN NUMBER OF DAYS WITH ACUTE HEADACHE MEDICATION PER 30-DAY PERIOD AFTER ADMINISTRATION OF BOTOX
MEAN CHANGE IN NUMBER OF DAYS
0
-2
-4
-6
-8
-10
-12
-0.7
-3.6
-5.0
-4.9
-5.0
-6.0
-6.2
-6.9
-7.2
-6.8
0
30
60
90
120
150
180
210
240
270
DAYS AFTER ENROLLMENT

FIG. 2

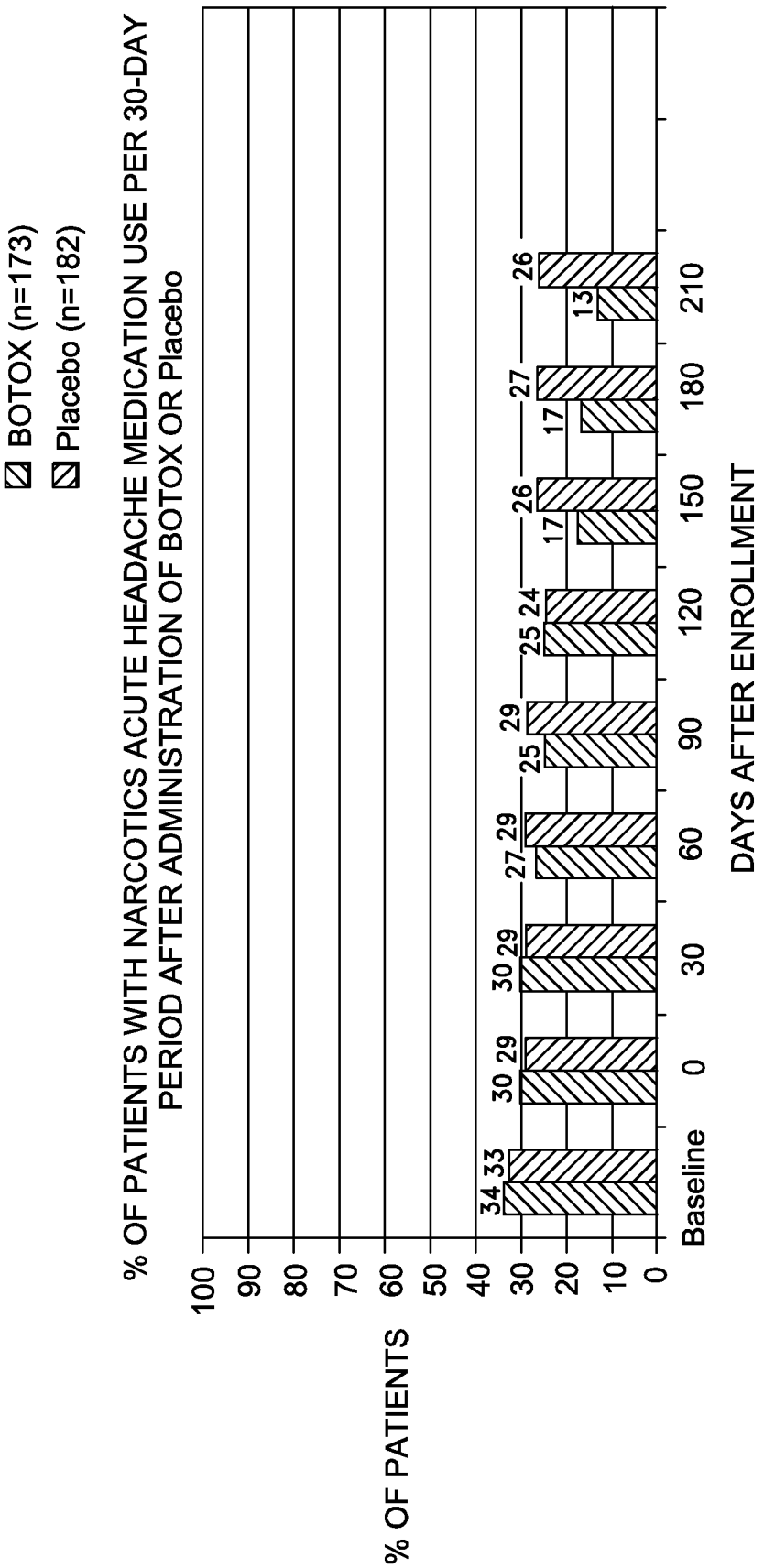

% OF PATIENTS WITH NARCOTICS ACUTE HEADACHE MEDICATION USE PER 30-DAY PERIOD AFTER ADMINISTRATION OF BOTOX OR Placebo
BOTOX (n=173)
Placebo (n=182)
% OF PATIENTS
100
90
80
70
60
50
40
30
20
10
0
34 33
30 29
30 29
27 29
25 29
25 24
17 26
17 27
13 26
Baseline
0
30
60
90
120
150
180
210
DAYS AFTER ENROLLMENT

FIG. 3

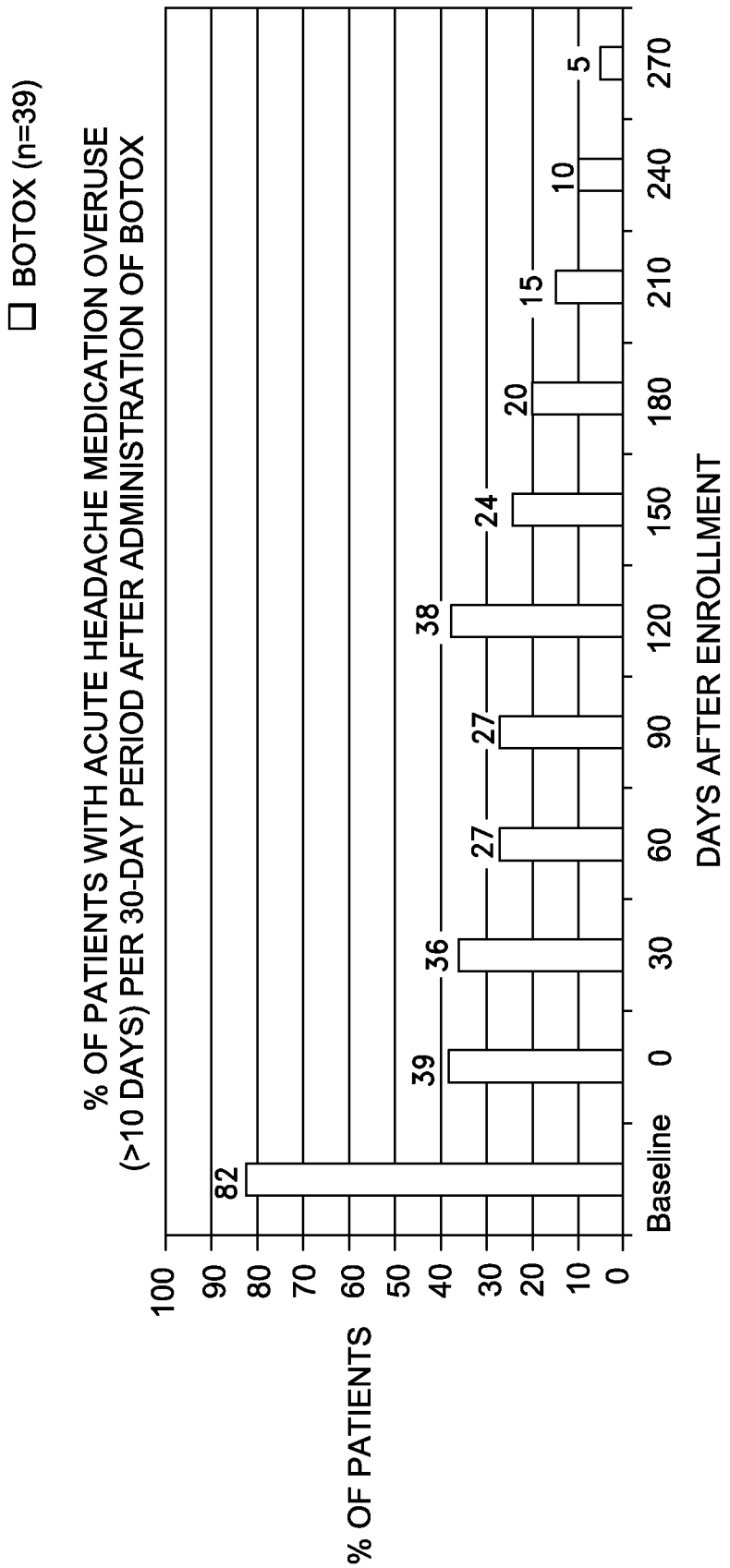

BOTOX (n=39)
% OF PATIENTS WITH ACUTE HEADACHE MEDICATION OVERUSE
(>10 DAYS) PER 30-DAY PERIOD AFTER ADMINISTRATION OF BOTOX
% OF PATIENTS
100
90
80
70
60
50
40
30
20
10
0
82
39
36
27
27
38
24
20
15
10
5
Baseline
0
30
60
90
120
150
180
210
240
270
DAYS AFTER ENROLLMENT

FIG. 4

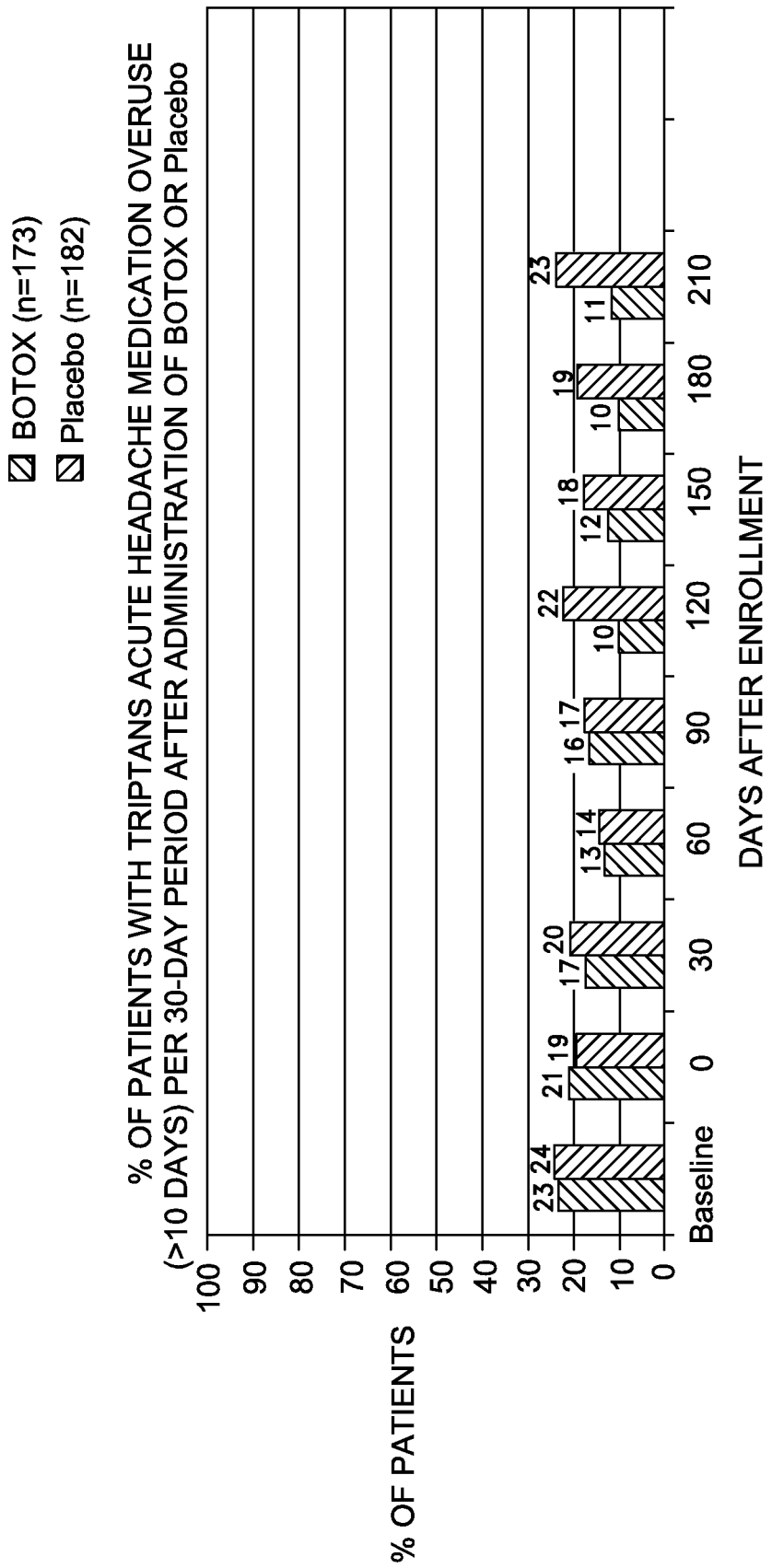

% OF PATIENTS WITH TRIPTANS ACUTE HEADACHE MEDICATION OVERUSE (>10 DAYS) PER 30-DAY PERIOD AFTER ADMINISTRATION OF BOTOX OR Placebo
BOTOX (n=173)
Placebo (n=182)
% OF PATIENTS
100
90
80
70
60
50
40
30
20
10
0
Baseline
0
30
60
90
120
150
180
210
DAYS AFTER ENROLLMENT
23 24
21 19
17 20
13 14
16 17
10 22
12 18
10 19
23
11

FIG. 5

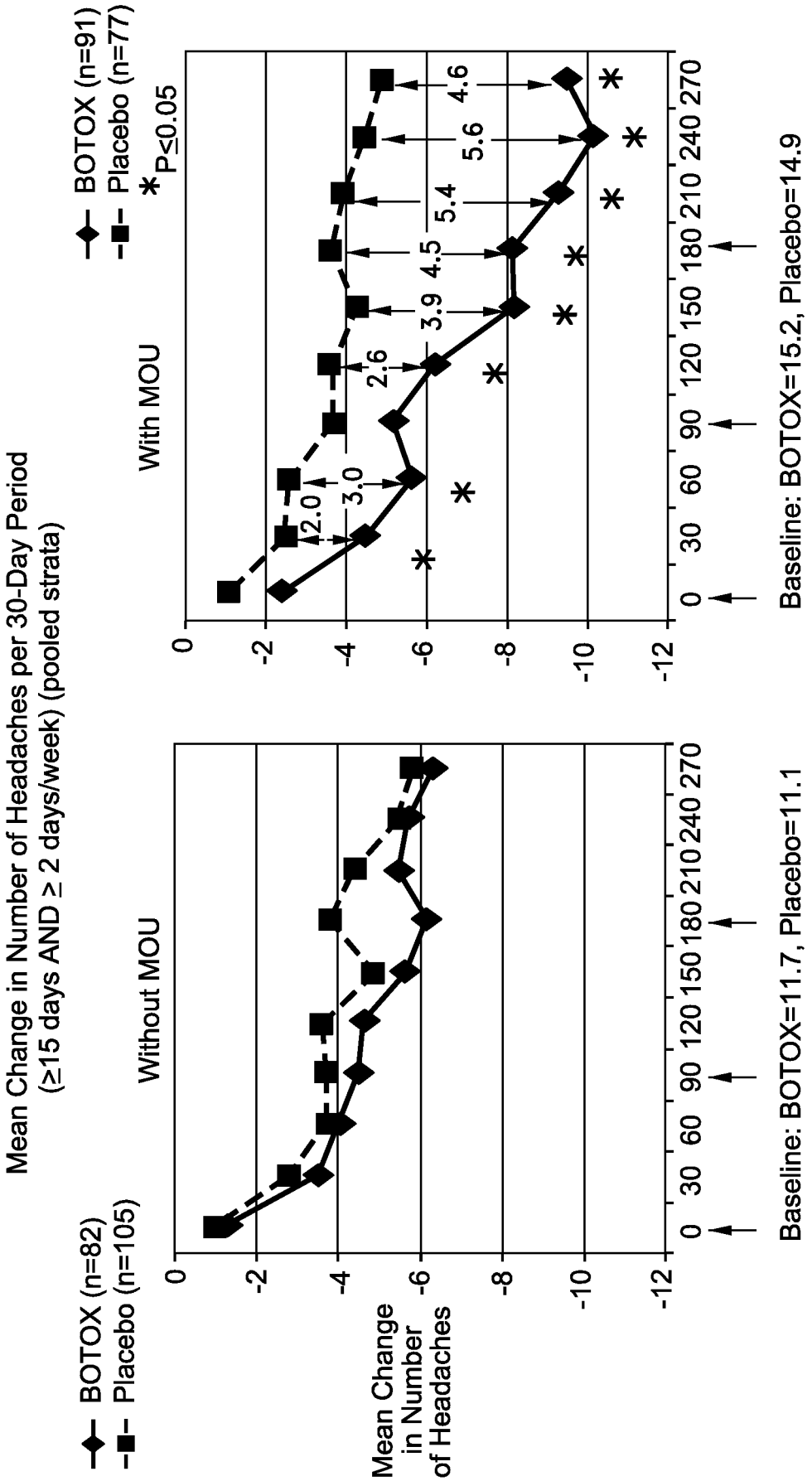

Mean Change in Number of Headaches per 30-Day Period
(≥15 days AND ≥ 2 days/week) (pooled strata)
BOTOX (n=82)
Placebo (n=105)
Without MOU
With MOU
BOTOX (n=91)
Placebo (n=77)
*P≤0.05
Mean Change in Number of Headaches
0
-2
-4
-6
-8
-10
-12
0 30 60 90 120 150 180 210 240 270
2.0
3.0
2.6
3.9
4.5
5.4
5.6
4.6
Baseline: BOTOX=11.7, Placebo=11.1
Baseline: BOTOX=15.2, Placebo=14.9

FIG. 6

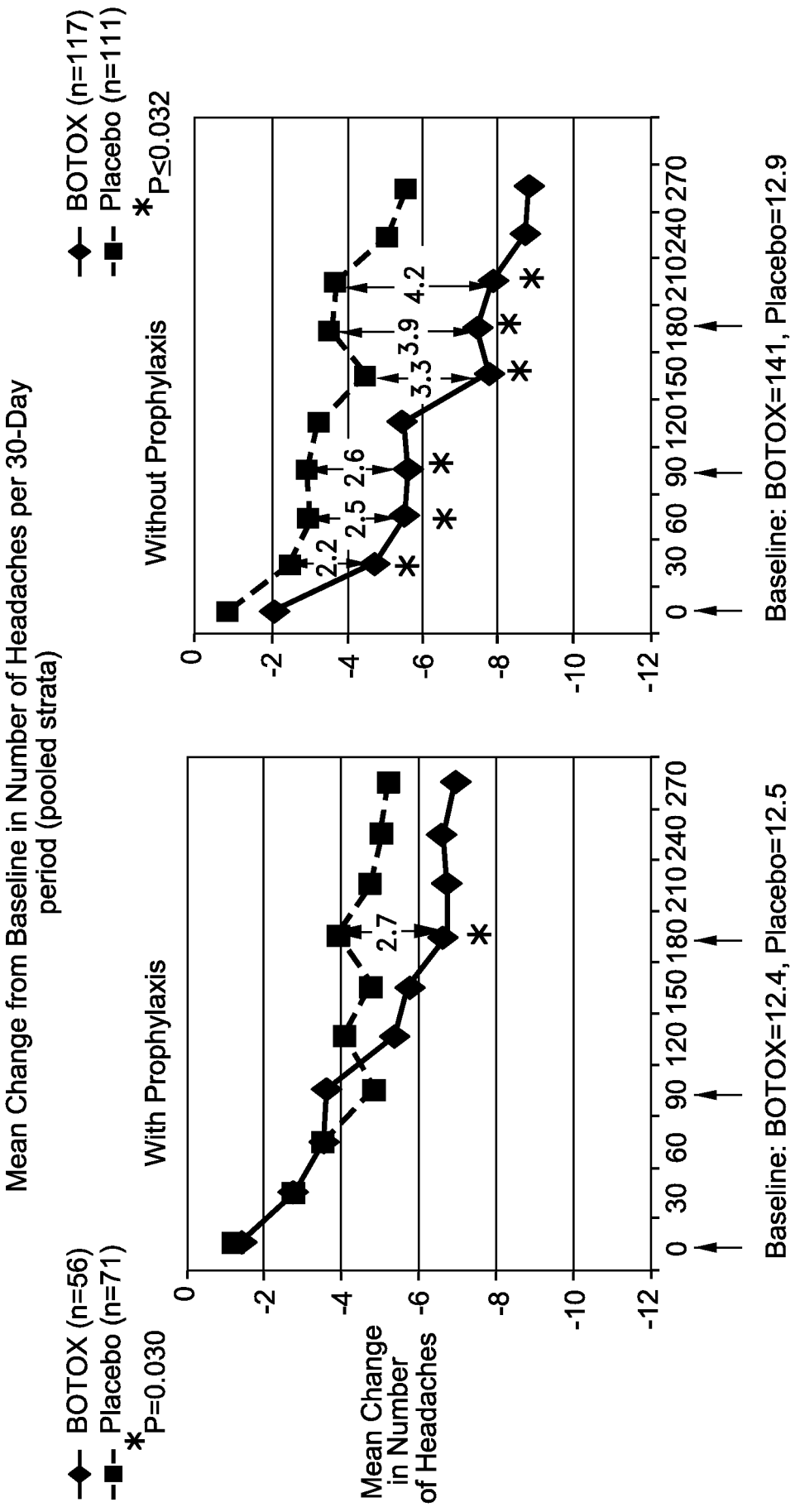

Mean Change from Baseline in Number of Headaches per 30-Day period (pooled strata)
BOTOX (n=56)
Placebo (n=71)
*P=0.030
BOTOX (n=117)
Placebo (n=111)
*P≤0.032
With Prophylaxis
Without Prophylaxis
Mean Change in Number of Headaches
0
-2
-4
-6
-8
-10
-12
0 30 60 90 120 150 180 210 240 270
2.7
2.2
2.5
2.6
3.3
3.9
4.2
Baseline: BOTOX=12.4, Placebo=12.5
Baseline: BOTOX=141, Placebo=12.9

FIG. 7

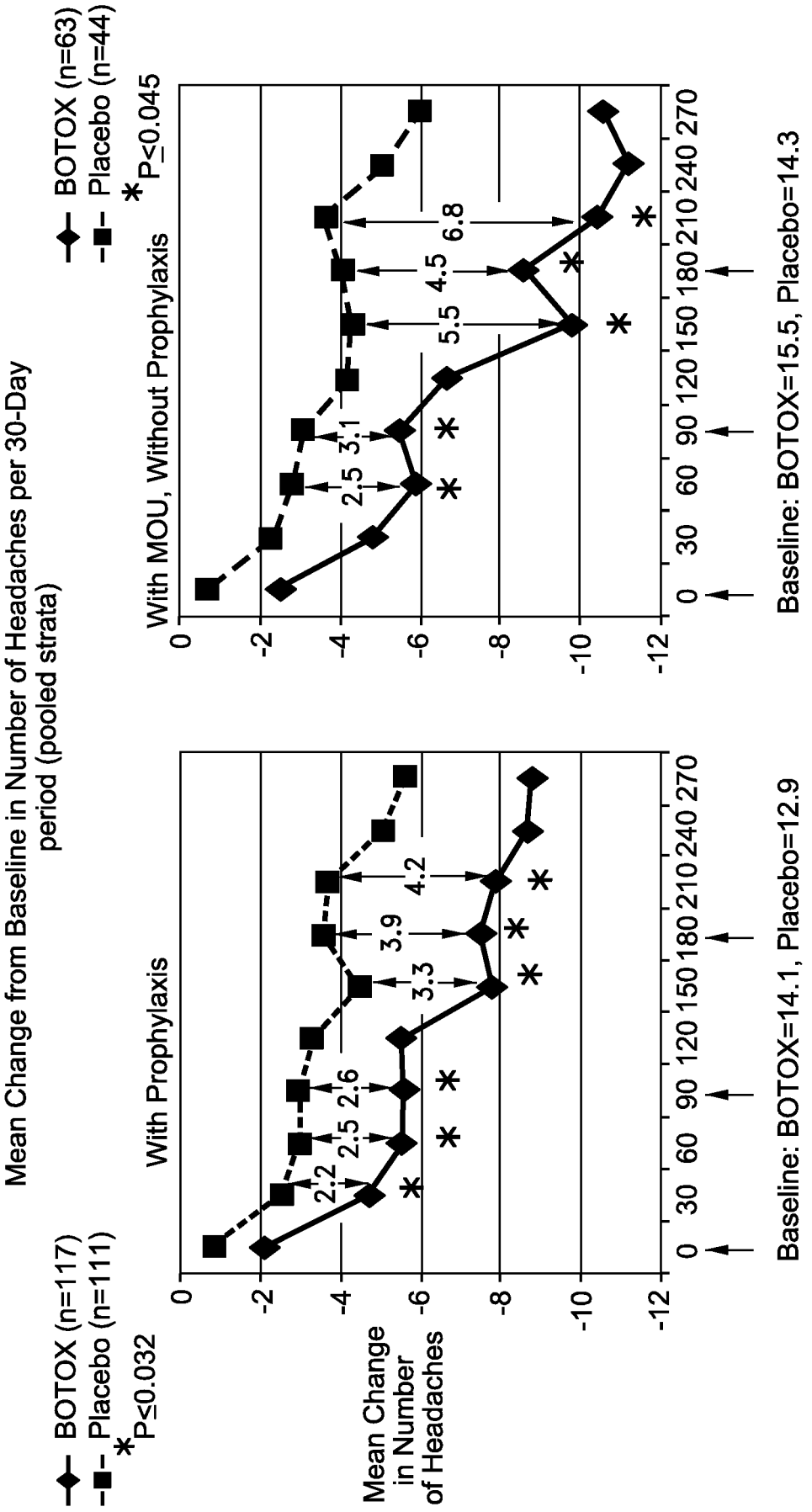

Mean Change from Baseline in Number of Headaches per 30-Day period (pooled strata)
BOTOX (n=117)
Placebo (n=111)
*P≤0.032
BOTOX (n=63)
Placebo (n=44)
*P≤0.045
With Prophylaxis
With MOU, Without Prophylaxis
Mean Change in Number of Headaches
0
-2
-4
-6
-8
-10
-12
0 30 60 90 120 150 180 210 240 270
2.2
2.5
2.6
3.3
3.9
4.2
2.5
3.1
5.5
4.5
6.8
Baseline: BOTOX=14.1, Placebo=12.9
Baseline: BOTOX=15.5, Placebo=14.3

FIG. 8

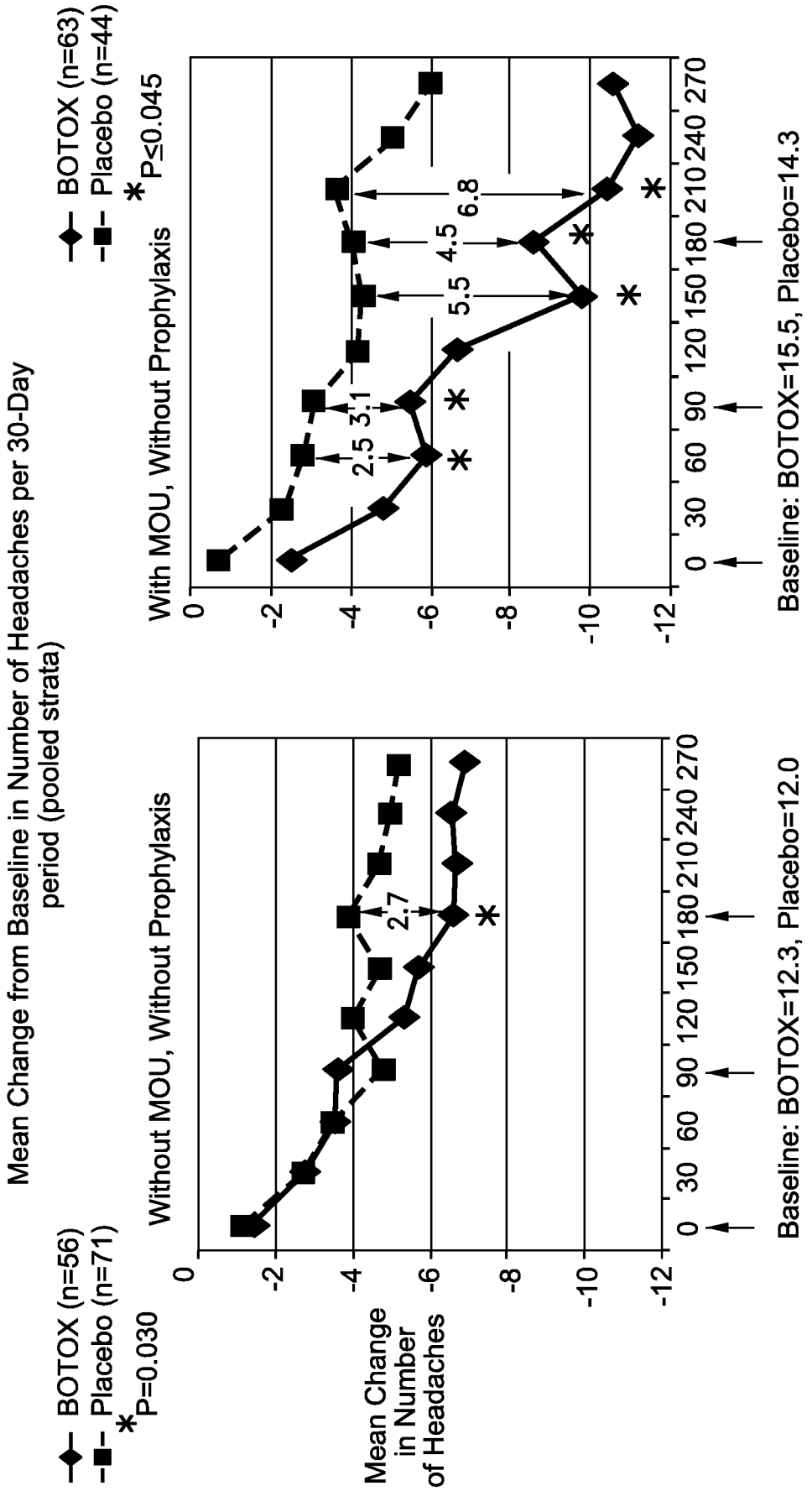

Mean Change from Baseline in Number of Headaches per 30-Day period (pooled strata)
BOTOX (n=56)
Placebo (n=71)
*P=0.030
Without MOU, Without Prophylaxis
Mean Change in Number of Headaches
0
-2
-4
-6
-8
-10
-12
2.7
*
0 30 60 90 120 150 180 210 240 270
Baseline: BOTOX=12.3, Placebo=12.0
BOTOX (n=63)
Placebo (n=44)
*P≤0.045
With MOU, Without Prophylaxis
2.5
3.1
5.5
4.5
6.8
*
*
*
*
Baseline: BOTOX=15.5, Placebo=14.3

FIG. 9

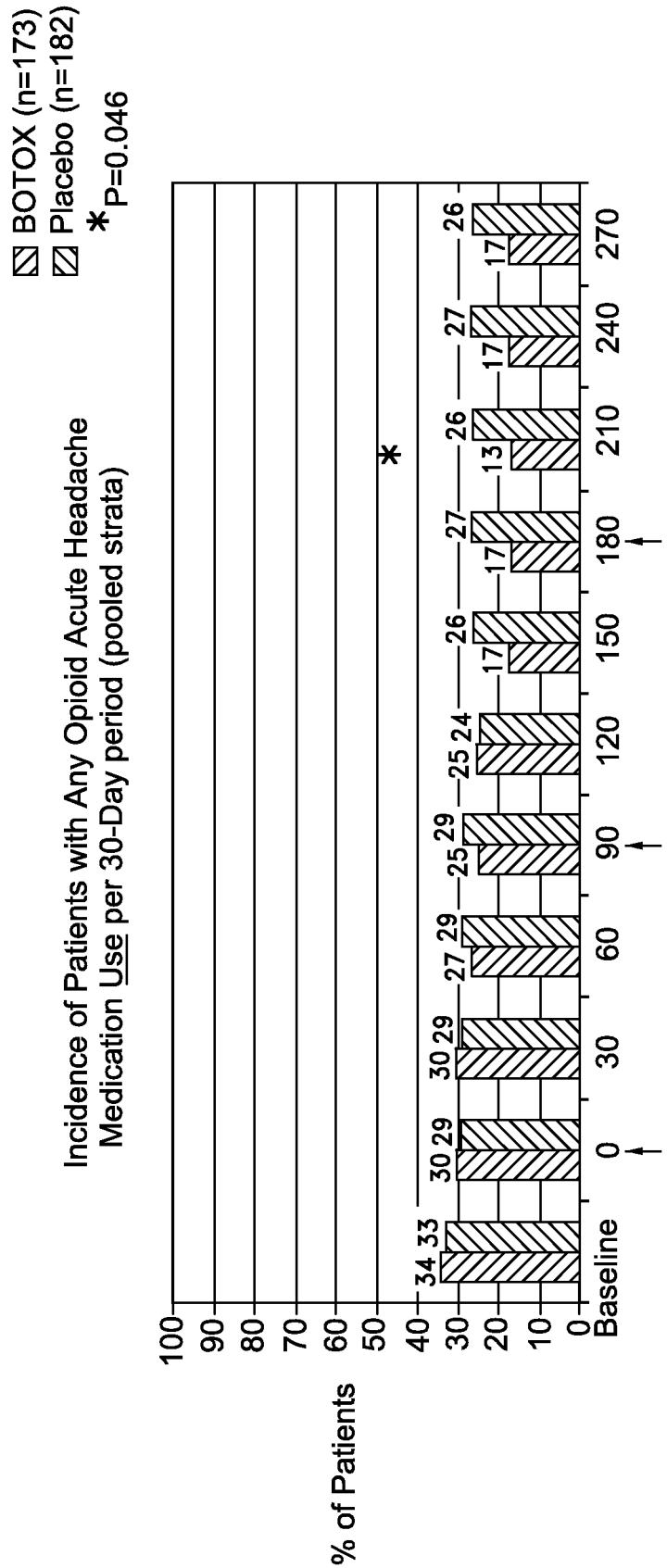

BOTOX (n=173)
Placebo (n=182)
*P=0.046
Incidence of Patients with Any Opioid Acute Headache Medication Use per 30-Day period (pooled strata)
% of Patients
Days after Enrollment
Baseline
0
30
60
90
120
150
180
210
240
270
100
90
80
70
60
50
40
30
20
10
0
34 33
30 29
30 29
27 29
25 29
25 24
17 26
17 27
13 26
17 27
17 26
17
*

FIG. 10

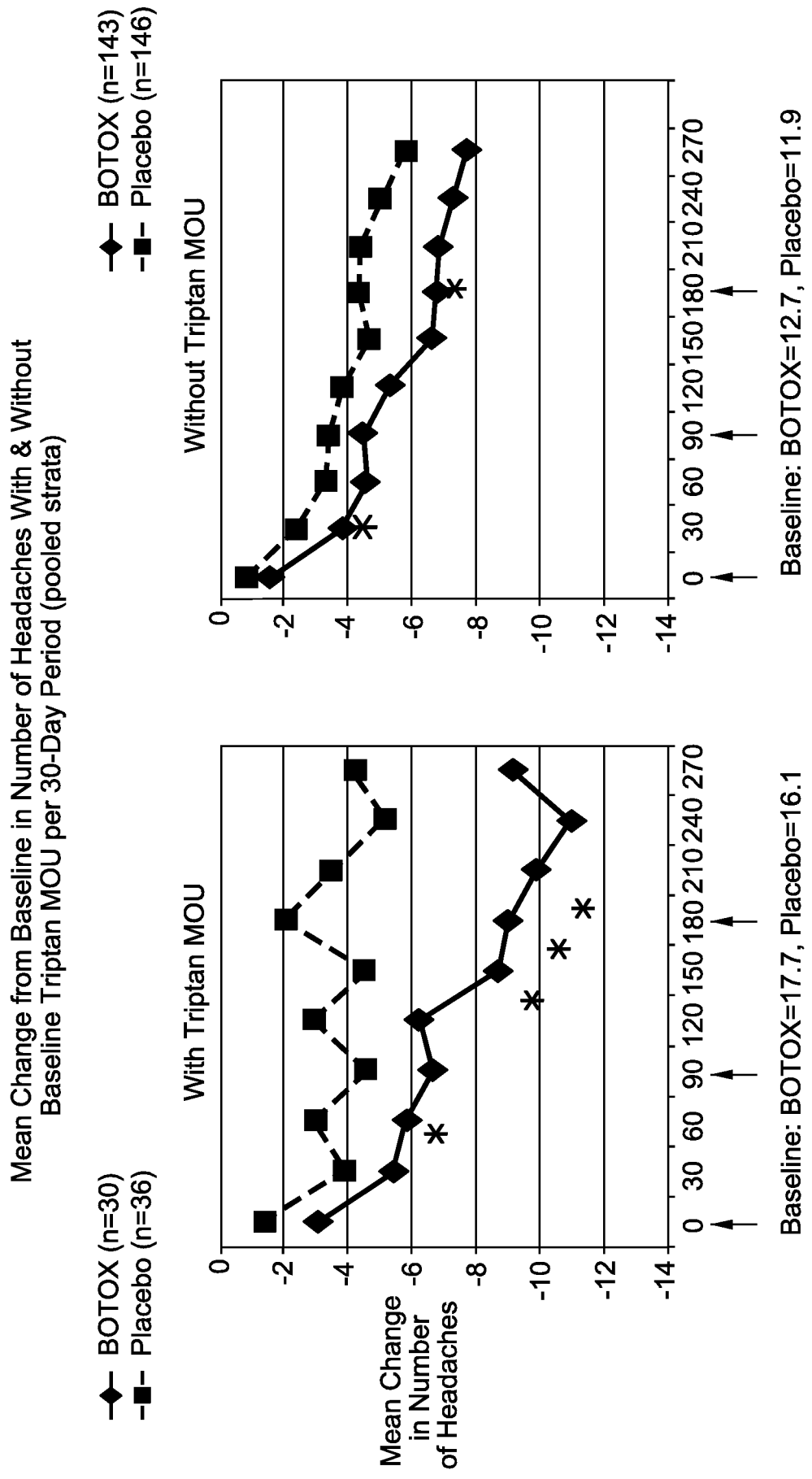

Mean Change from Baseline in Number of Headaches With & Without Baseline Triptan MOU per 30-Day Period (pooled strata)
BOTOX (n=30)
Placebo (n=36)
BOTOX (n=143)
Placebo (n=146)
With Triptan MOU
Without Triptan MOU
Mean Change in Number of Headaches
0
-2
-4
-6
-8
-10
-12
-14
0 30 60 90 120 150 180 210 240 270
Baseline: BOTOX=17.7, Placebo=16.1
Baseline: BOTOX=12.7, Placebo=11.9

FIG. 11

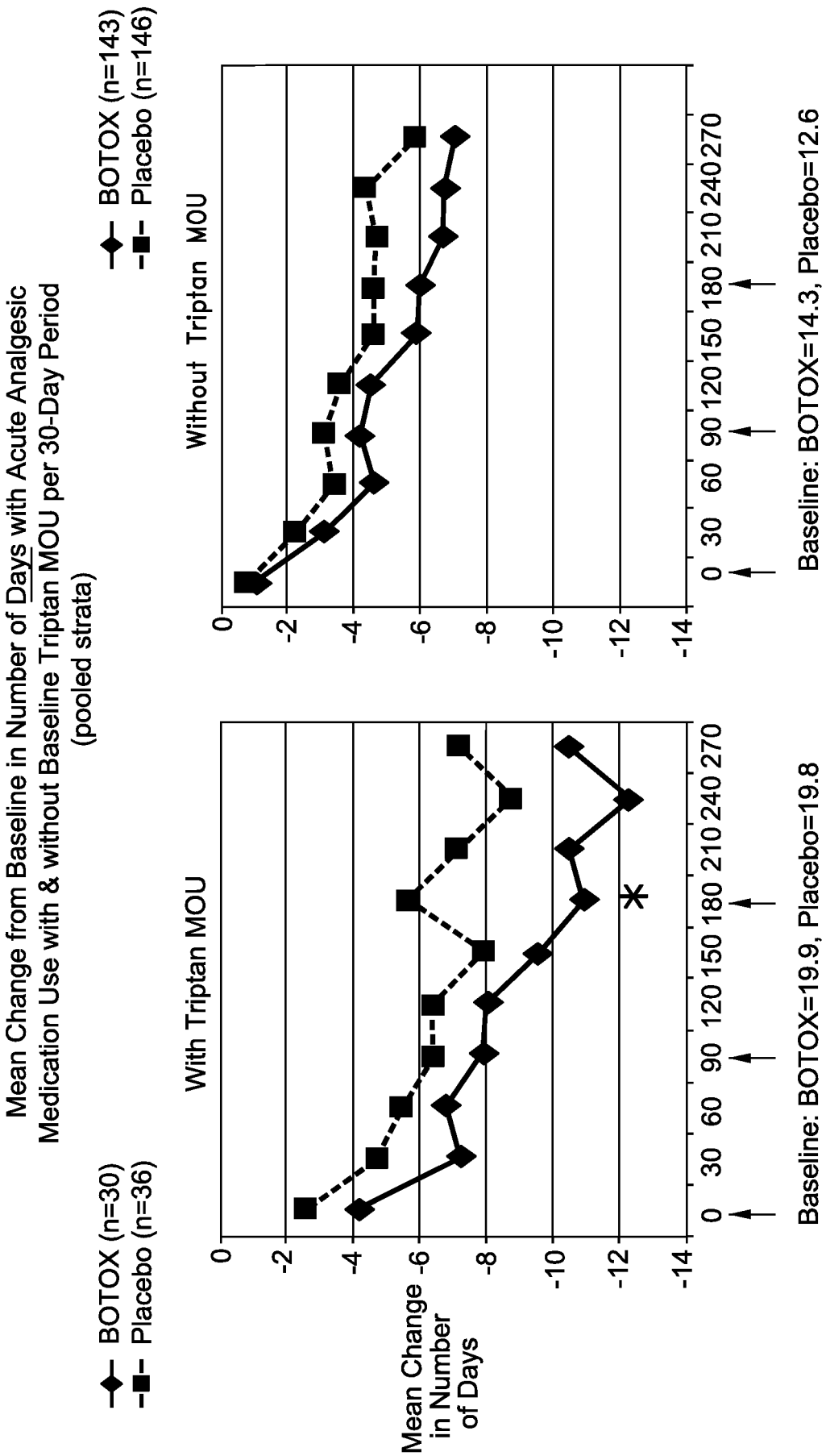

Mean Change from Baseline in Number of Days with Acute Analgesic Medication Use with & without Baseline Triptan MOU per 30-Day Period (pooled strata)
BOTOX (n=30)
Placebo (n=36)
BOTOX (n=143)
Placebo (n=146)
With Triptan MOU
Without Triptan MOU
Mean Change in Number of Days
0
-2
-4
-6
-8
-10
-12
-14
0 30 60 90 120 150 180 210 240 270
*
Baseline: BOTOX=19.9, Placebo=19.8
Baseline: BOTOX=14.3, Placebo=12.6

FIG. 12

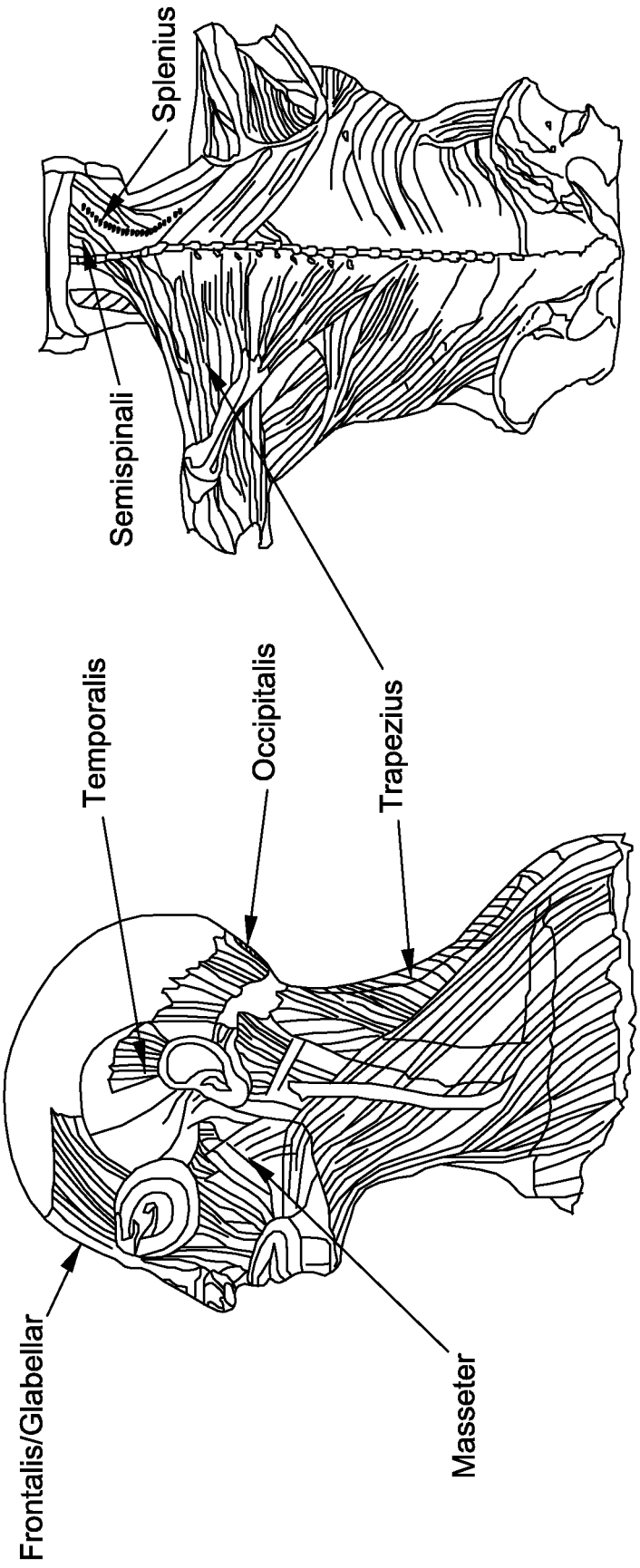


Illustration of the Face and Sites to Inject for Treatments 1, 2, 3 and 4.

FIG. 13

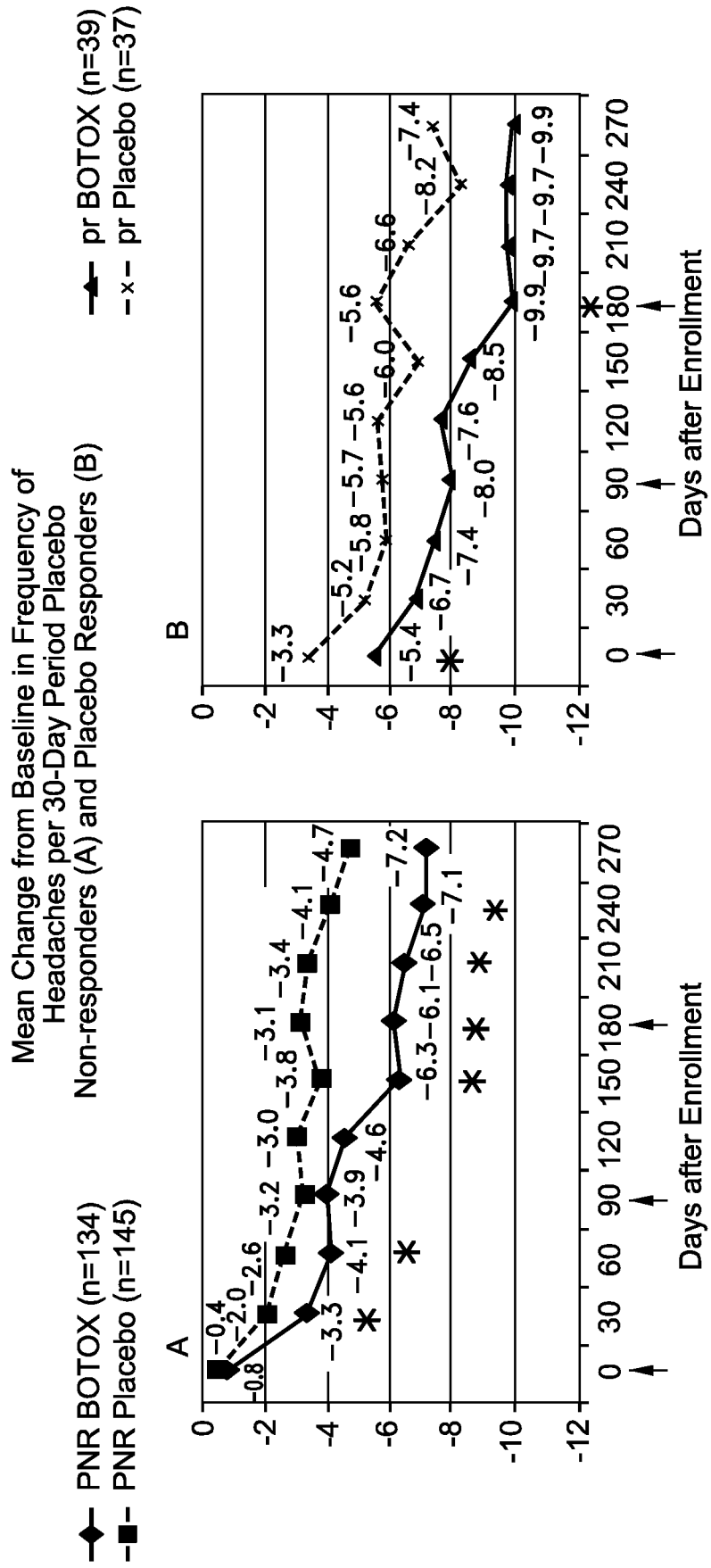

Mean Change from Baseline in Frequency of Headaches per 30-Day Period Placebo Non-responders (A) and Placebo Responders (B)
PNR BOTOX (n=134)
PNR Placebo (n=145)
pr BOTOX (n=39)
pr Placebo (n=37)
A
B
Days after Enrollment
PNR = placebo non-responders, pr = placebo responders.
Baseline: PNR BOTOX = 13.1, PNR placebo = 12.8 , pr BOTOX = 15.0, pr placebo = 12.3 headaches
*p≤0.050
Arrows indicate when dosing occurred (post placebo run-in)

FIG. 14

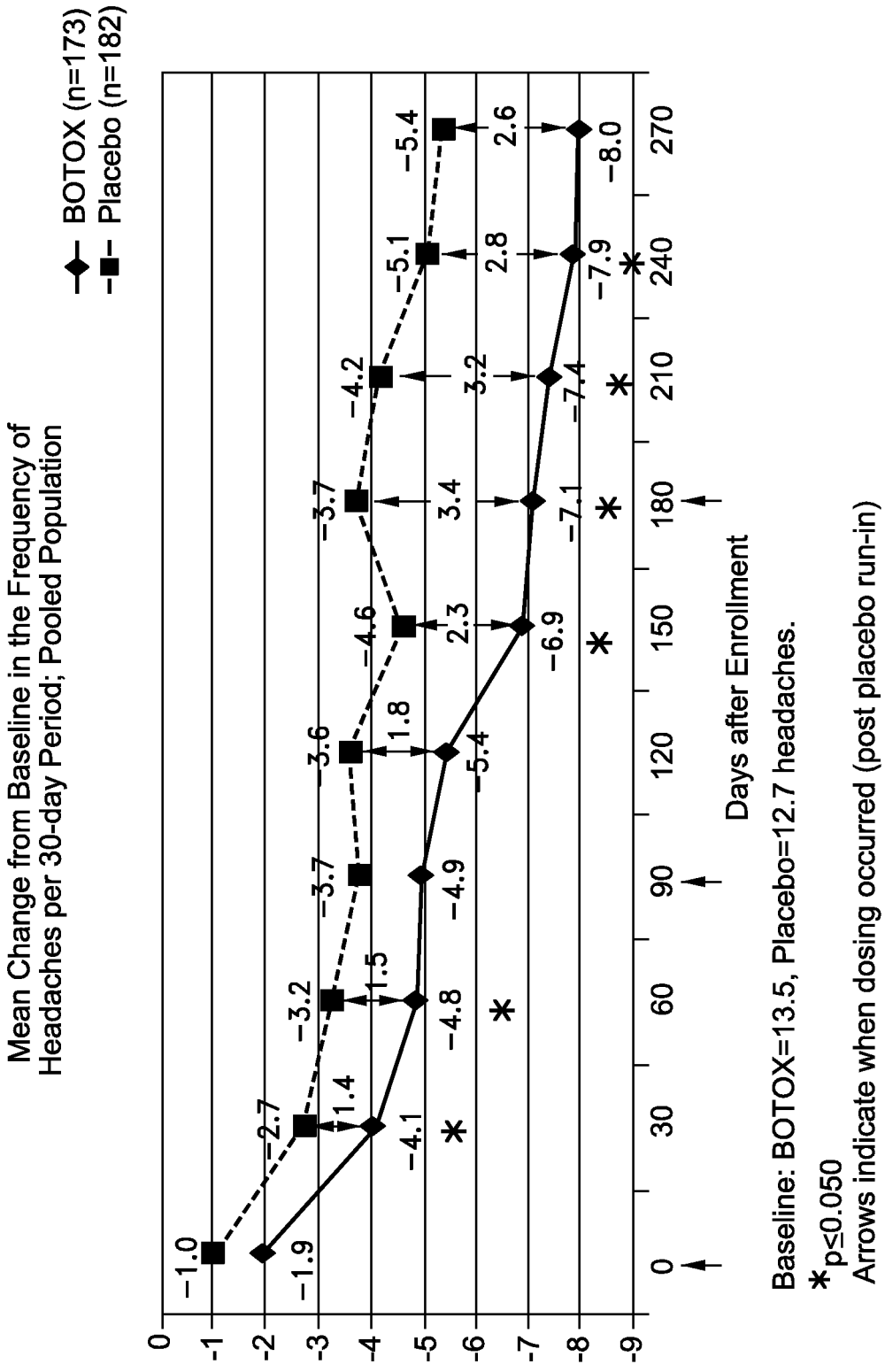

Mean Change from Baseline in the Frequency of Headaches per 30-day Period; Pooled Population
BOTOX (n=173)
Placebo (n=182)
0
-1
-2
-3
-4
-5
-6
-7
-8
-9
0
30
60
90
120
150
180
210
240
270
Days after Enrollment
-1.0
-1.9
-2.7
-3.2
-3.7
-3.6
-3.7
-4.2
-5.1
-5.4
-4.1
-4.8
-4.9
-5.4
-6.9
-7.1
-7.4
-7.9
-8.0
1.4
1.5
1.8
2.3
3.4
3.2
2.8
2.6
*
Baseline: BOTOX=13.5, Placebo=12.7 headaches.
*p≤0.050
Arrows indicate when dosing occurred (post placebo run-in)

FIG. 15

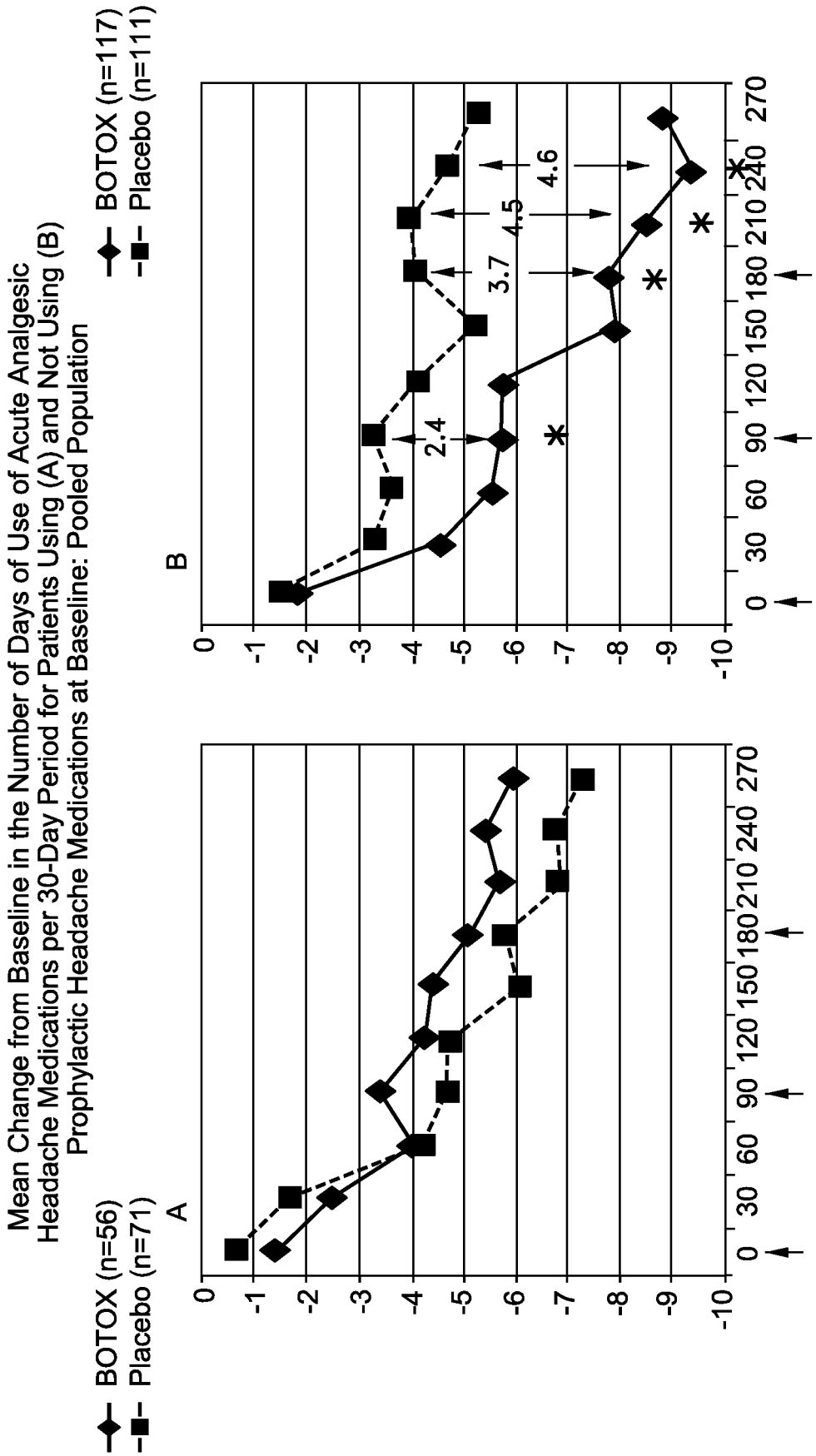

Mean Change from Baseline in the Number of Days of Use of Acute Analgesic
Headache Medications per 30-Day Period for Patients Using (A) and Not Using (B)
Prophylactic Headache Medications at Baseline: Pooled Population
BOTOX (n=56)
Placebo (n=71)
BOTOX (n=117)
Placebo (n=111)
A
B
0
-1
-2
-3
-4
-5
-6
-7
-8
-9
-10
0 30 60 90 120 150 180 210 240 270
2.4
3.7
4.5
4.6
*
Baseline: With prophylaxis BOTOX = 14.9, days with prophylaxis placebo = 14.8 days, without prophylaxis BOTOX =15.5 days, without prophylaxis placebo = 13.5 days of use.
*p≤0.050
Arrows indicate when dosing occurred (post placebo run-in)

FIG. 16

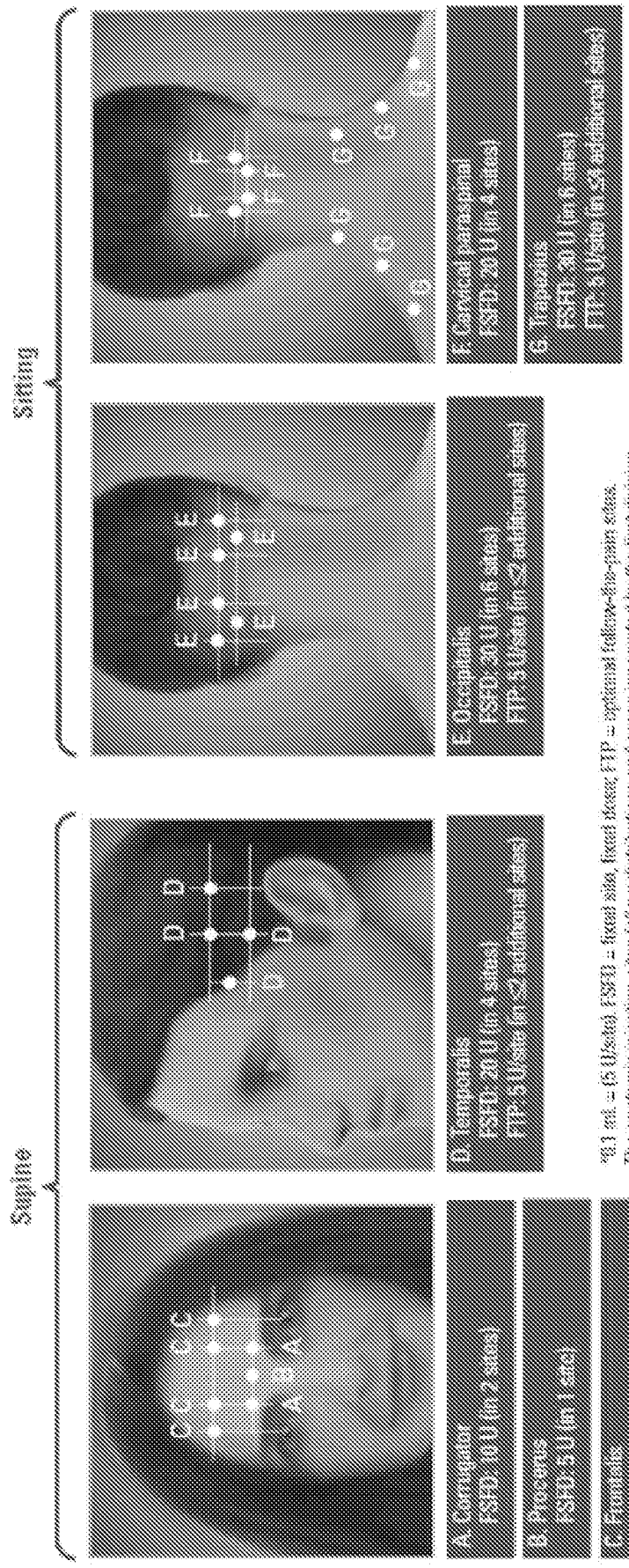

Supine
Sitting
A Cervical
[STD 10 U (in 2 sites)]
B Parotid
[STD 10 U (in 1 site)]
C Tonsils
[STD 20 U (in 4 sites)]
D Temporalis
[STD 20 U (in 1 site)
FTP 10 Units (in 2 additional sites)]
E Occipitalis
[STD 20 U (in 1 site)
FTP 10 Units (in 2 additional sites)]
F Cervical paraspinal
[STD 20 U (in 1 site)]
G Trapezius
[STD 30 U (in 2 sites)
FTP 10 Units (in 2 additional sites)]
*(1 ml. = 10 Units); STD = fixed dose; FTP = optional follow-the-pain sites.
The anatomic injection sites follow distributions and areas innervated by the first division of the trigeminal nerve and the second cervical nerve.

FIG. 17