Study REC-15-016

A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Evaluation of the Efficacy and Safety of IV Meloxicam (N1539) Following Bunionectomy

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Study REC-15-016

Phase III Bunionectomy

- Multicenter, Multi-dose, Randomized, Double-blind, Placebo-controlled

- 201 subjects randomized to either IV Meloxicam (N1539) 30 mg or Placebo
  - Study medication administered q24 hours up to 3 doses
  - 95% of subjects completed the 48 hour assessments

- Standard analgesia design
  - Pain Intensity assessments (SPID48 = Primary Endpoint)
  - Use of rescue medication
  - Time to onset
  - Patient Global Assessment of Pain Control

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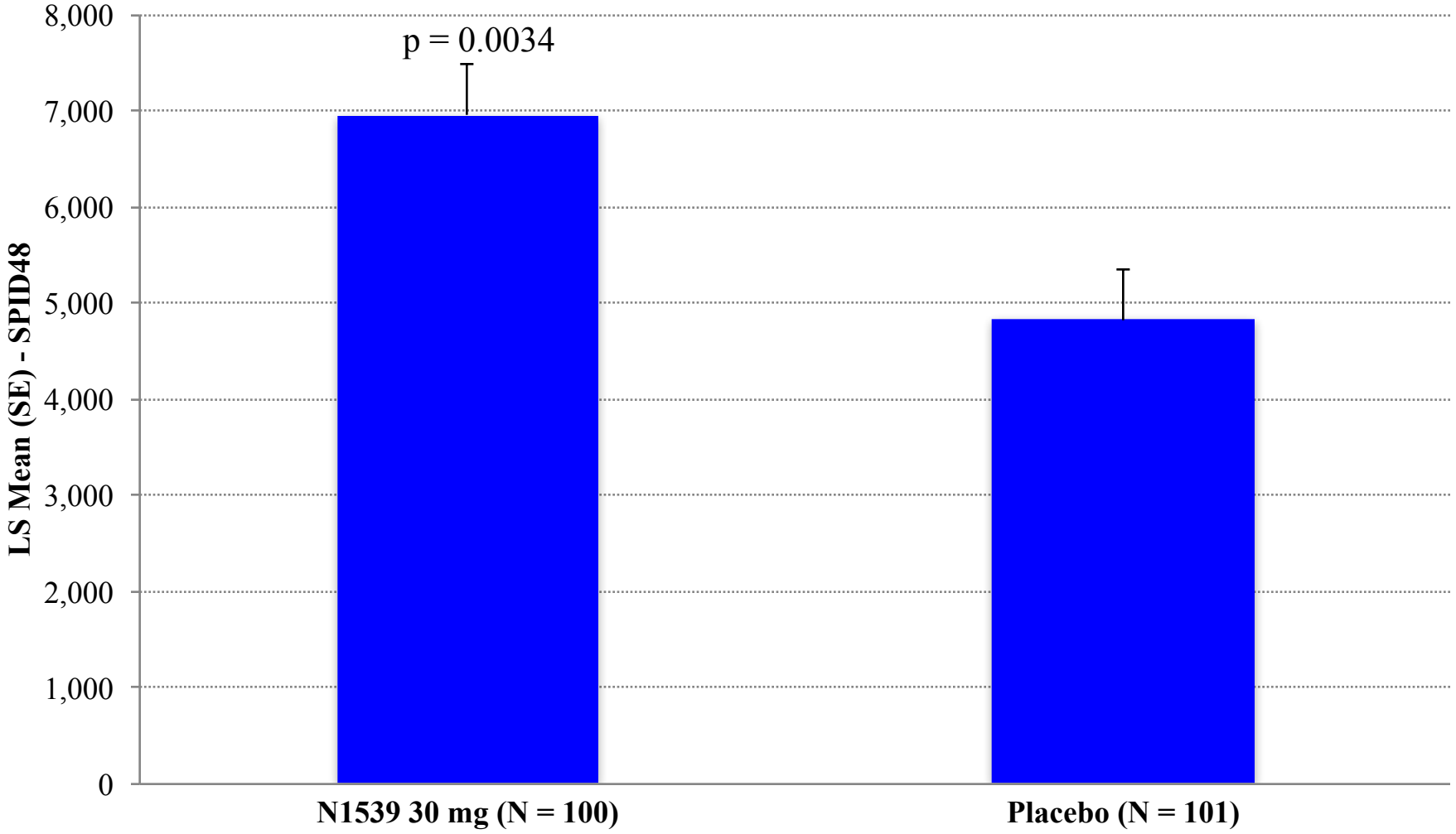
Primary Endpoint – SPID48



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Summary of Secondary Endpoints

Parameter	p-value
SPID6	0.0153
SPID12	0.0053
SPID24	0.0084
SPID24-48	0.0050
Time to First Rescue Analgesia	0.0076
Number of Subjects Rescued 0-24 Hours	0.0002
Number of Subjects Rescued 24-48 Hours	0.0009
Number of Subjects Rescued 0-48 Hours	0.0002
Number of Times Rescued 0-24 Hours	0.0025
Number of Times Rescued 24-48 Hours	0.0108
Number of Times Rescued 0-48 Hours	0.0014
% Subjects with >30% Improvement - 6 Hours	0.0451
% Subjects with >30% Improvement - 24 Hours	0.0107
% Subjects with >50% Improvement - 24 Hours	0.0430
PGA of Pain Control at 48 hours	0.0046

Times to Perceptible and Meaningful Pain Relief, % Subjects with >50% Improvement within 6 Hours, PGA of Pain Control at 24 hours were not significantly different between treatment groups.

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Adverse Events – ≥3% in either group

Preferred Term	n (%) of Subjects N1539 30 mg (N=100)	Placebo (N=101)
Subjects with ≥ 1 TEAE	44 (44.0)	54 (53.5)
Nausea	20 (20.0)	26 (25.7)
Headache	8 (8.0)	12 (11.9)
Vomiting	3 (3.0)	9 (8.9)
Pruritus	8 (8.0)	3 (3.0)
Decreased appetite	2 (2.0)	7 (6.9)
Constipation	4 (4.0)	5 (5.0)
Abdominal pain	--	6 (5.9)
Dizziness	3 (3.0)	4 (4.0)
Flushing	3 (3.0)	1 (1.0)
Somnolence	3 (3.0)	2 (2.0)
ALT increased	--	3 (3.0)

**Two (2) subjects experienced Serious Adverse Events during this study. Both subjects were randomized to placebo.

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