A Randomized Open-Label Study Comparing Rapid and Standard Inductions to Injectable Buprenorphine Extended-release (BUP-XR) Treatment

Category: Oral Presentation

Abstract Body
Introduction

This randomized sub-study, nested within the open-label phase of a double-blinded randomized study (NCT04995029), evaluated treatment retention using standard induction (SI) vs. rapid induction (RI) onto BUP-XR injection in treatment-seeking participants who frequently inject opioids or use fentanyl/high doses of opioids. We report results from the induction interim analysis.

Methods

Participants were randomized at a 2:1 ratio to RI (a single dose of 4 mg transmucosal [TM] buprenorphine [BUP]) or SI (7-14 days of TM-BUP) before BUP-XR injection 1. Randomization was stratified by the same-day urine drug screen fentanyl result (98/140 positive). The primary endpoint, retention rate difference at injection 2 (administered 1 week after injection 1), was estimated by a Bayesian approach. The posterior probability was evaluated for non-inferiority (NI) of RI to SI using a 10% NI margin against 96% critical value for 1-sided Type I error <10%. Investigator assessed precipitated opioid withdrawal (POW) was reported.

Results

137 out of 140 randomized participants initiated treatment with TM-BUP (48/49 SI, 89/91 RI). RI was non-inferior to SI: Retention rates at injection 2 were 59.6% SI vs. 67.1% RI, with 7.5% difference (95% highest posterior density: -8.7 to 24.5%). Estimated posterior probabilities for RI-SI > -10% and RI superior to SI were 98.2% and 80.9%, respectively. The proportion of participants with POW was 16.9% RI vs. 14.6% SI. In RI, POW was not more serious or long-lasting, and did not result in increased discontinuation compared to SI.

Between injections 2 and 3, no individual adverse event was observed in ≥5% of participants.

Conclusion

Compared to standard induction, rapid induction had comparable outcomes for treatment retention and precipitated opioid withdrawal in this high-risk population. Administration of injection 2 one week after injection 1 was safe and well tolerated. The shorter time necessary for RI may increase feasibility of BUP-XR treatment.

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Key Words

- Opioids/Opiates

Learning Objective # 1
A rapid induction protocol may be a feasible option for high-risk users (inject opioids or use fentanyl/high doses of opioids).

Learning Objective # 2
The second injection of BUP-XR can be safely administered one week after the first injection.

Reference # 1
Not applicable

Reference # 2
Not applicable

Lead Author
Rajinder Shiwach
Principal Investigator | Insite Clinical Research

Co-Author
Bernard Le Foll
Staff Physician and Lead of Translational Addiction Research Program | Centre for Addiction and Mental Health

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Co-Author
Kelly Dunn
Professor | The Johns Hopkins University School of Medicine

Co-Author
Hannu Alho
Professor of Addiction Medicine, Emeritus | University of Helsinki

Co-Author
Stephanie Strafford
Clinical Program Lead Research & Development | Indivior Inc.

Co-Author
Dr. Yue Zhao
Director, Biostatistics Research & Development | Indivior Inc.

Co-Author
Robert Dobbins
Medicines Development Lead, Drug Discovery & Translational Medicines | Indivior Inc.