

# Extending the treatment options in alcohol dependence

## Student EBM presentations

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## Drug recommended to help cut drink dependence



The pill reduces the urge to drink alcohol



# The question

## **Scenario:**

Mrs. Jones, a 35 year old lady, visited her GP previously due to her dependence on alcohol but refused psychiatric support as treatment. She has recently heard that NICE has approved a new drug, nalmefene, to help reduce alcohol consumption and asks her GP whether it might be appropriate for her.

## **Clinical question:**

Does the drug nalmefene help to reduce alcohol consumption in previously untreated adults with alcohol dependence?



# The question

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## Clinical question:

Does the drug nalmefene help to reduce alcohol consumption in previously untreated adults with alcohol dependence?

<b>P</b>	Patients who are dependent on alcohol, who have not been treated previously
<b>I</b>	The drug nalmefene
<b>C</b>	A placebo drug and/or the best current psychiatric support
<b>O</b>	Patients have a reduced alcohol consumption and reduced dependence

# The search and search results

The image shows a screenshot of the PubMed Clinical Queries search interface. The search query "treatment alcohol dependence nalmefene" is entered in the search box. The search results are displayed in two columns. The left column shows 15 results, and the right column shows 8 results. A red box highlights the search query, and another red box highlights the search results. A red arrow points from the search query to the search results. A red box highlights the search results, and a red arrow points from the search results to the search query. A red box highlights the search results, and a red arrow points from the search results to the search query.

**PubMed Clinical Queries**  
Results of searches on this page are limited to specific clinical research areas. For corr

Search query: **treatment alcohol dependence nalmefene**

**Clinical Study Categories**  
Category: Therapy  
Scope: **Narrow**

**Systematic Reviews**

**Results: 5 of 15**  
Efficacy of as-needed nalmefene in alcohol-dependent patients with at least a high drinking risk level: results from a subgroup analysis of two randomized controlled 6-month studies.  
van den Brink W, Aubin HJ, Bladström A, Torup L, Gual A, Mann K. Alcohol Alcohol. 2013 Sep-Oct; 48(5):570-8. Epub 2013 Jul 19.  
A randomised, double-blind, placebo-controlled, efficacy study of nalmefene, as-needed use, in patients with alcohol dependence.  
Gual A, He Y, Torup L, van den Brink W, Mann K, ESENSE 2 Study Group. Eur Neuropsychopharmacol. 2013 Nov; 23(11):1432-42. Epub 2013 Apr 3.  
**Extending the treatment options in alcohol dependence: a randomized controlled study of as-needed nalmefene.**  
Mann K, Bladström A, Torup L, Gual A, van den Brink W. Biol Psychiatry. 2013 Apr 15; 73(8):706-13. Epub 2012 Dec 11.  
Predicting response to opiate antagonists and placebo in the treatment of pathological gambling.  
Grant JE, Kim SW, Hollender F, Potenza MN

**Results: 5 of 8**  
Emerging pharmacotherapies for alcohol dependence: a systematic review  
Aubin HJ, Daepfen J. Drug Alcohol Depend. 2010 Dec 8; 112(1-2):1-11. Epub 2010 Dec 8.  
Opioid antagonists for pharmacological treatment of alcohol dependence - a critical review.  
Soyka M, Rösner S. Curr Drug Abuse Rev. 2008 Nov; 1(3):280-91.  
Opioid antagonists for alcohol dependence.

**Extending the treatment options in alcohol dependence: a randomized controlled study of as-needed nalmefene.**  
Mann K, Bladström A, Torup L, Gual A, van den Brink W. Biol Psychiatry. 2013 Apr 15; 73(8):706-13. Epub 2012 Dec 11.

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# The study

- Compared 18mg as-needed nalfemene/placebo over a 24 week period in conjunction with BRENDA
- Primary outcome was total number of heavy drinking days per month in addition the amount of alcohol consumed
- The paper concluded nalfemene has a clinically significant benefit

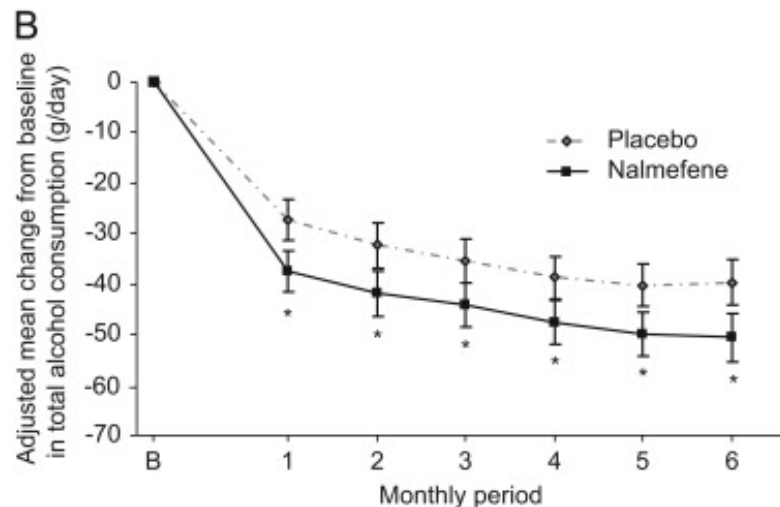
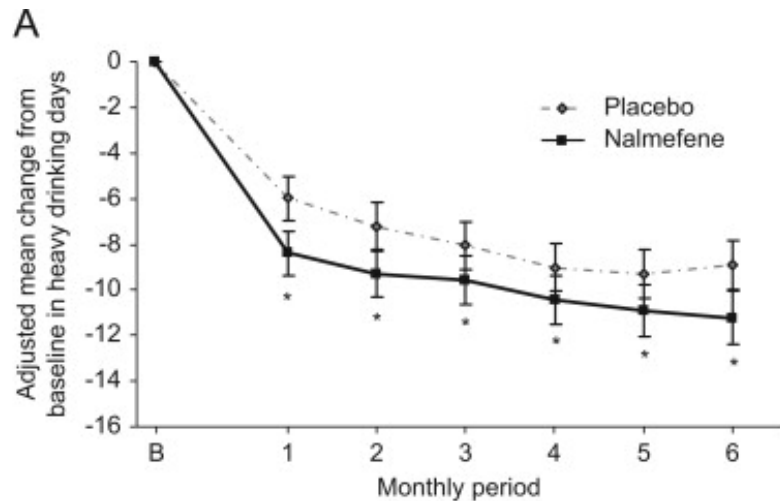


# The study appraisal

Recruitment	Were the subjects representative of the target population?
Allocation	How was the randomisation carried out? Was allocation concealed?
Maintenance	Were the groups equal at the start? And maintained through equal management and f/u?
Blinding (measurement)	Were the outcomes measured with blinded assessors/participants?
Objective outcomes (measurement)	Were there differences in how outcomes were determined?



# The Results (interpretation of findings)



Placebo	289	289	263	251	235	222	213
Nalmefene	290	290	249	217	185	165	152

**Table 3.** Adverse Events in All-Patients-Treated Set

	Placebo (n = 296)	Nalmefene (n = 302)
Treatment-Emergent Adverse Events <sup>a</sup>	198 (66.9)	246 (81.5)
Treatment-Emergent Adverse Events (≥5%)		
Dizziness	23 (7.8)	83 (27.5)
Nausea	18 (6.1)	83 (27.5)
Fatigue	25 (8.4)	53 (17.5)
Headache	27 (9.1)	36 (11.9)
Nasopharyngitis	37 (12.5)	34 (11.3)
Sleep disorder	1 (.3)	32 (10.6)
Insomnia	10 (3.4)	30 (9.9)
Vomiting	8 (2.7)	24 (7.9)
Hyperhidrosis	5 (1.7)	16 (5.3)
Treatment-Emergent Adverse Events Leading to Dropout <sup>a</sup>	22 (7.4)	69 (22.8)
Treatment-Emergent Adverse Events Leading to Dropout (≥2%)		
Dizziness	0 (.0)	16 (5.3)
Nausea	0 (.0)	16 (5.3)
Fatigue	0 (.0)	10 (3.3)
Headache	0 (.0)	9 (3.0)
Serious Adverse Events <sup>b</sup>	20 (6.7) <sup>c</sup>	18 (5.9)



# The Implications

- Quality of analysis
- Involvement of the sponsor
- High risk of adverse events
- Implications for the patient?