

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 dependance?



The question

Scenario:

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Clinical question:

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

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



The search and search results

PubMed.gov
US National Library of Medicine
National Institutes of Health

NCBI Resources How To

PubMed Clinical Queries

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

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.

Results: 5 of 8

Emerging pharmacotherapies for alcohol dependence: a systematic review.

Aubin HJ, Daepen J, Drug Alcohol Depend. Opioid antagonists. Yancey JR, Lumbard Am Fam Physician. 2013 Mar 1; 87(5):353-60. Opioid antagonists. Rösner S, Haig H, Soyka M. Cochrane Database Syst Rev. 2010 Dec 8; (12):CD001867. 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.

Predicting response to opiate antagonists and placebo in the treatment of pathological gambling.

Grant JE, Kim SW, Hollander E, Potenza MN.

Clinical Queries

Topic-Specific Queries

Systematic Reviews

CEBM

Red boxes highlight the search terms "treatment alcohol dependence nalmefene", the "Clinical Study Categories" section, the "Systematic Reviews" section, and the abstract of the study by Mann K et al. Red arrows point from the "Clinical Study Categories" section to the "Systematic Reviews" section, and from the abstract of the study by Mann K et al. to the "Systematic Reviews" section.

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

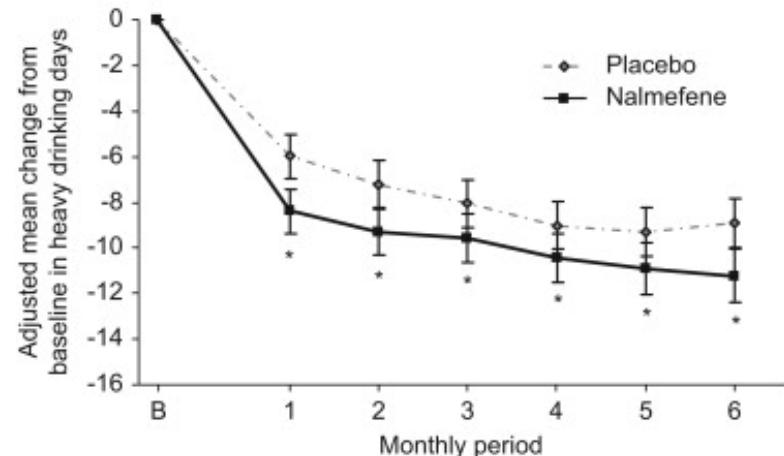
The study appraisal

| 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? |

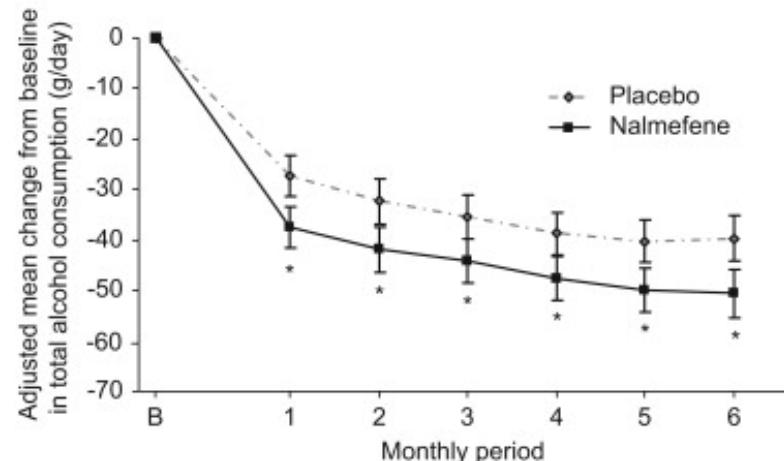


The Results (interpretation of findings)

A



B



| | | | | | | | |
|-----------|-----|-----|-----|-----|-----|-----|-----|
| 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 ^a | 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 ^a | 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 ^b | 20 (6.7) ^c | 18 (5.9) |

The Implications

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