NKR 40: PICO 9 *Bør patienter med nyopståede lænderygsmerter tilbydes opioider i tillæg til vanlig behandling?*

Review information

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Abstract

Background

Objectives

Search methods

Selection criteria

Data collection and analysis

Main results

Authors' conclusions

Characteristics of studies

Characteristics of included studies

Friedman 2015

Methods	**Study design:** Randomized controlled trial **Study grouping:** **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Intervention Kontrol **Included criteria:** Adults aged 21 to 64 years who presented to the ED primarily formanagement of acute LBP, defined as pain originatingbetween the lower border of the scapulae and the upper glutealfolds, and received a diagnosis consistent with nontraumaticnonradicular, musculoskeletal LBP. Patients wererequired to have functionally impairing back pain, which wedefined as a score of greater than 5 on the Roland-MorrisDisability Questionnaire (RMDQ) **Excluded criteria:** radicular pain, which we defined as pain radiating below thegluteal folds, direct trauma to the back within the previousmonth, pain duration for more than 2 weeks, or recent historyof greater than 1 LBP episode per month. We alsoexcluded patients who were pregnant or lactating, unavailablefor follow-up, with allergy or contraindication to theinvestigational medications, or had chronic opioid use currentlyor in the past **Pretreatment:** Eneste parameter der skiller sig ud er "Duration of LBP...", hvor gruppen der får placebo i gennemsnit har haft LBP i 48 timer, mens gruppen der får opioid har haft smerter et døgn længere (72t.) - og der er her en lille overvægt af kvinder 46:64 m/k, mens der i placebo gruppen er 50:50

Interventions	**Intervention Characteristics** Intervention ● *oxycodone, 5 mg/acetaminophen, 325 mg, to be taken as 1 or 2 tablets every 8 hours*: x ● *placebo, to be taken as 1 or 2 tablets every 8 hours*: 0 ● *naproxen, twenty 500-mg tablets, taken as 1 every 12 hours*: x ● *10- minute educational intervention based on information from the National Library of Medicine*: x Kontrol ● *oxycodone, 5 mg/acetaminophen, 325 mg, to be taken as 1 or 2 tablets every 8 hours*: 0 ● *placebo, to be taken as 1 or 2 tablets every 8 hours*: x ● *naproxen, twenty 500-mg tablets, taken as 1 every 12 hours*: x ● *10- minute educational intervention based on information from the National Library of Medicine*: x
Outcomes	*Funktionsevne (Disability) 0-12 uger* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: Roland Morris ● **Range**: 0-24 ● **Unit of measure**: None ● **Direction**: Lower is better ● **Data value**: Endpoint
Identification	**Sponsorship source:** Not reported **Country:** USA **Setting:** Emergency department **Comments:** All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported. **Authors name:** Benjamin W. Friedman et al **Institution:** Department of Emergency Medicine, Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, New York **Email:** bwfriedmanmd @gmail.com **Address:** BenjaminW.Friedman, MD,MS, Department ofEmergency Medicine, MontefioreMedical Center, Albert EinsteinCollege of Medicine, 111 E 210th St,Bronx, NY 10467

Notes	*Fagkonsulent Nkr40* on 21/03/2016 20:11 **Included** Protokol tilgængelig via URL *Ture Karbo* on 28/03/2016 08:33 **Interventions** I: Naproxen+ Oxycodone-acetaminophenK: Naproxen+ Placebo *Ture Karbo* on 28/03/2016 09:23 **Outcomes** Primary outcome: improvement in RMDQ between ED visit and 1-week follow-upDer mangler plads til resp. RMDQ-improvement efter 3 mdr. Intervention = 4.6 (3.2 to 6.1) Kontrol = 3.8 (2.6 to 5.1)

Risk of bias table

Bias	Authors' judgement	Support for judgement
Allocation concealment	Low risk	
Incomplete outcome data	Low risk	
Selective outcome reporting	Low risk	
Blinding of participants and personnel	Low risk	
Sequence Generation	Low risk	Judgement Comment: The pharmacisit performed a stratified randomization in block of 6 based on 2 sequences using a randomization plan generator
Other sources of bias	Low risk	Judgement Comment: None
Blinding of outcome assessors	Low risk	Judgement Comment: Patient reported outcome measure - patients blinded

Footnotes

References to studies

Included studies

Friedman 2015

Friedman,Benjamin W.; Dym,Andrew A.; Davitt,Michelle; Holden,Lynne; Solorzano,Clemencia; Esses,David; Bijur,Polly E.; Gallagher,E. John. Naproxen With Cyclobenzaprine, Oxycodone/Acetaminophen, or Placebo for Treating Acute Low Back Pain: A Randomized Clinical Trial.. JAMA 2015;314(15):1572-1580. [DOI: http://dx.doi.org/10.1001/jama.2015.13043]

Data and analyses

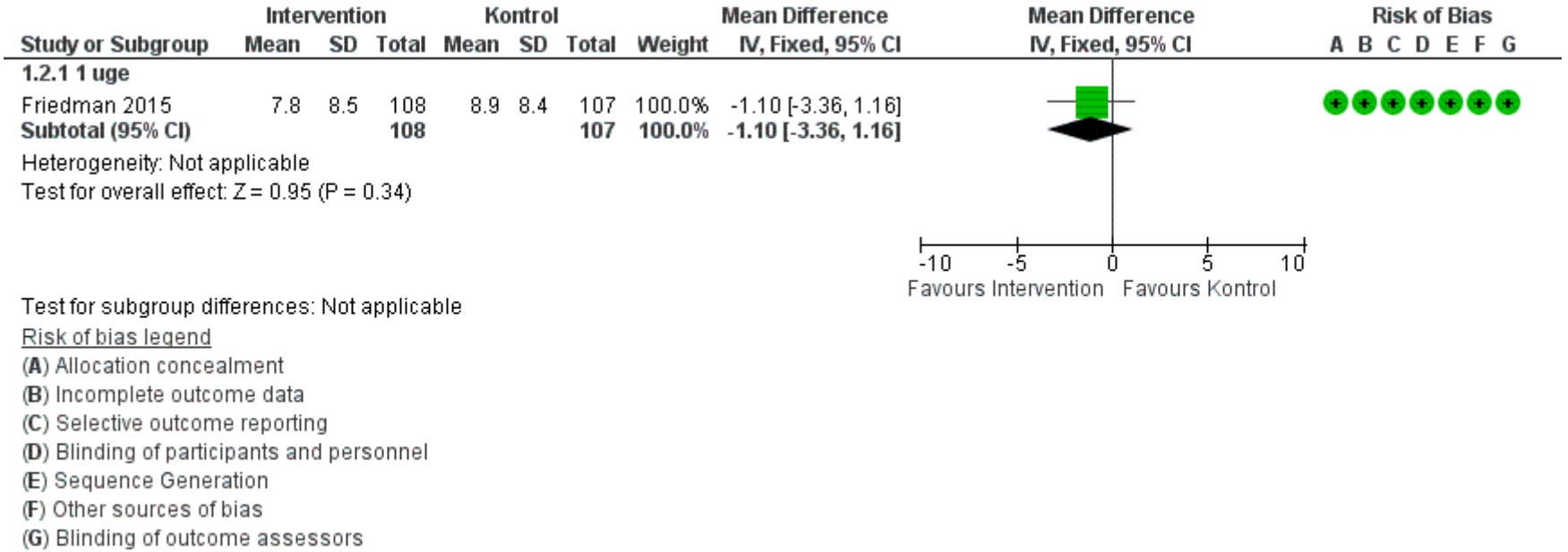
1 Intervention vs Kontrol

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Smerteniveau 0-12 uger	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.2 Funktionsevne (Disability) 0-12 uger	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.2.1 1 uge	1	215	Mean Difference (IV, Fixed, 95% CI)	-1.10 [-3.36, 1.16]
1.3 Alvorlige bivirkninger 0-12 uger	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.4 Livskvalitet 6-18 måneder	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.5 Recidiv 6-18 måneder	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.6 Sygefravær antal dage - 6-18 måneder	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.7 Sygefravær Proportion i arbejde - 6-18 måneder	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.8 Frafald generelt - efter endt behandling	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable

1.9 Frafald bivirkninger - efter endt behandling	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable

Figures

Figure 1 (Analysis 1.2)



Forest plot of comparison: 1 Intervention vs Kontrol, outcome: 1.2 Funktionsevne (Disability) 0-12 uger.