VRAAG 5D: Pruritus

Systematic reviews

Study ID	Method	Patient characteristics	Intervention(s)	Results	Critical appraisal of review quality
Gooding 2010	• SR • Funding/CoI: No Financial disclosures reported • Search date: until April 2008 • Databases: Medline, Embase, Amed, Cinahl and the Cochrane Library • Study designs: RCTs • N included studies: 6 studies	• Eligibility criteria: participants on haemodialysis suffering from pruritus	Topical capsaicin vs. Placebo	Pruritus: CRITICAL OUTCOME No combination of data (meta-analysis) carried out Quality of life: CRITICAL OUTCOME No combination of data (meta-analysis) carried out	• Review of good quality • Included RCTs: Breneman (1992), Yu-Li Cho (1996), Targ (1996)
Xander 2013	• SR • Funding/CoI: declare no CoI • Search date: August 2012 • Databases: The Cochrane Library, MEDLINE, EMBASE, BIOSIS, CINAHL, PsycINFO • Study designs: Randomised controlled trials • N included studies: 38 studies including 1286 participants	• Eligibility criteria: adult palliative care patients with pruritus	Pharmacological treatments (30 different treatments included) vs. placebo/ not treatment/ alternative treatment	Pruritus: CRITICAL OUTCOME MA results Pruritus on VAS scale: Nalfurafine vs. placebo: SMD=-0.46 ; 95%CI (-0.65; -0.28) Gabapentin vs. placebo: MD=-5.20 ; 95%CI (-6.7; -3.7) Capsaicin vs. placebo: MD=-0.80 ; 95%CI (-1.34 ; -0.25) Other results narratively presented Quality of life: CRITICAL OUTCOME Not reported	• Review of good quality • Included RCTs: Legroux-Crespel (2004), Pauli-Magnus (2000), Peer (1996), Wilkstrom (2005a), Wilkstrom (2005b), Kumagai (2010), Ashmore (2000), Murphy (2003), Ozaykan (2001), Gunal (2004), Naini (2007), Pour-Reza-Gholi (2007), Silverberg (1977), Silva (1994), Nasrollahi (2007), Pederson (1980), Makhlough (2010), Duque (2005)

Primaire studies

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Boaz 2009	• Design: Randomized controlled trial • Funding/CoI: Funding from Ahava Dead Sea Laboratories/ 2 authors employees at Ahava Dead Sea Laboratories	• Eligibility criteria: haemodialysis patients with uremic pruritus • *A priori* patient characteristics: intervention vs. control ○ Age mean: 67.8 ○ Male 57%	Dead Sea minerals enriched body lotion (n=25) vs. Placebo 1 (identical to	Pruritus: CRITICAL OUTCOME Post treatment severity score (5-point Likert) Itching (p=0.44) P1: 0.5 P2: 1 DS: 1	Level of evidence: unclear risk of bias • Unclear allocation concealment • Double-blind study

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	• Setting: Institute of Nephrology,E. Wolfson Medical Center, Israel • Sample size: N=78 • Duration: 14 days	○ Diabetes 33.8%	treatment, but without dead sea minerals, n=25) vs. Placebo 2 (lotion without active ingredients, n=28)	Tightness (p=0.70) P1: 0 P2: 0 DS: 0 Dryness (p=0.22) P1: 1 P2: 2 DS: 1 Peeling (p=0.51) P1: 0 P2: 0 DS: 0 Change from baseline severity score Itching (p=0.42) P1: 0 P2: 0 DS: 0 Tightness (p=0.81) P1: 0 P2: 0 DS: 0 Dryness (p=0.60) P1: -0.5 P2: 0 DS: -1 Peeling (p=0.24) P1: -0.5 P2: 0 DS: 0 <u>Quality of life</u>: CRITICAL OUTCOME Not reported	
Ko 2011	• Design: Randomized controlled trial • Funding/CoI: Research grant to one author: NTUHYL.97.S011/ no CoIs declared • Setting: Yun-Lin Branch,Taiwan • Sample size: N=21 • Duration: 12 weeks	• Eligibility criteria: patients with chronic kidney disease, refractory uraemic pruritus • *A priori* patient characteristics: intervention vs. control ○ Age mean: 60 years ○ Male 52% ○ Diabetes mellitus: 33%	Narrowband ultraviolet B (NB-UVB) phototherapy (n=11) vs. Long-wave UVA (n=10)	<u>Pruritus</u>: CRITICAL OUTCOME Pruritus VAS (mean change from baseline) Week 3 (between group: p=0.76) NB-UVB: -1.71 (-3.27; -0.14) Control: -1.43 (-2.63; -0.22) Week 6 (between group: p=0.92) NB-UVB: -3.53 (-6.02; -1.03) Control: -3.38 (-5.54; -1.21) Week 9 (between group: p=0.89)	Level of evidence: high risk of bias • Unclear allocation concealment • Single blinded • 3 dropouts, no ITT analysis

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				NB-UVB: -3.06 (-5.03;-1.08) Control: -3.24 (-5.56; -0.92) Week 12 (between group: p=0.24) NB-UVB: -3.91 (-6.17;-1.64) Control: -2.24 (-4.25;-0.23) Quality of life: CRITICAL OUTCOME Not reported	
Lin 2012	• Design: prospective quasi-experimental design • Funding/CoI: Grant No. DOH100-TD-C-111-002/ no CoI • Setting: Taiwan • Sample size: N=93 • Duration: 3 weeks	• Eligibility criteria: Haemodialysis patients with uremic pruritus • *A priori* patient characteristics: intervention vs. control ○ Age mean: 62years ○ Male 59% ○ Mean intensity of uremic pruritus: mild	Chilled baby-oil (n=30) vs. Un-chilled baby-oil (n=31) vs. Control (n=32)	Pruritus: CRITICAL OUTCOME Scores from Itch Severity Scale: pre-post-test Difference: Group1:3.81 (3.18) Group2:3.11 (2.45) Control :1.04 (2.47) Frequency: Group1: Pre 0.49 (0.22) Post 0.28 (0.19) Group2: Pre 0.54 (0.24) Post 0.33 (0.22) Control : Pre 0.36 (0.16) Post 0.24 (0.16) Sensibility: Group1: Pre 0.34 (0.25) Post 0.09 (0.10) Group2: Pre 0.23 (0.24) Post 0.11 (0.18) Control : Pre 0.08 (0.14) Post 0.08 (0.15) Area: Group1: Pre 0.52 (0.23) Post 0.32 (0.28) Group2: Pre 0.62 (0.27) Post 0.40 (0.30) Control : Pre 0.41 (0.27) Post 0.36 (0.30) Level: Group1: Pre 0.53 (0.20) Post 0.33 (0.17) Group2: Pre 0.51 (0.19) Post 0.32 (0.15) Control : Pre 0.38 (0.17) Post 0.31 (0.18) Emotion: Group1: Pre 0.18 (0.15) Post 0.07 (0.11) Group2: Pre 0.14 (0.16) Post 0.10 (0.14) Control : Pre 0.09 (0.21) Post 0.05 (0.12) Sex: Group1: Pre 0.10 (0.31) Post 0.00 (0.00) Group2: Pre 0.06 (0.25) Post 0.00 (0.00) Control : Pre 0.03 (0.18) Post 0.03 (0.18) Sleep: Group1: Pre 0.41 (0.31) Post 0.23 (0.26) Group2: Pre 0.44 (0.24) Post 0.23 (0.27)	Level of evidence: high risk of bias • Quasi-randomisation

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				Control : Pre 0.20 (0.21) Post 0.13 (0.18) Quality of life: CRITICAL OUTCOME Not reported	
Marquez 2012	• Design: Randomized open-label cross-over trial • Funding/CoI: no CoI; funding not reported • Setting: Argentina • Sample size: N=22 • Duration: 60 days	• Eligibility criteria: patients with chronic hemodialysis with uremic pruritus • *A priori* patient characteristics: intervention vs. control ○ Age mean: 54y ○ Time on HD: 4.9y	Desloratadine 5 mg, 3x/wk for 3wks vs. Gabapentin 300 mg, 3x/wk for 3 wks	Pruritus: CRITICAL OUTCOME VAS-score for pruritus Baseline: 5.95 Gabapentin: 4.6 (p=0.07) Wash-out: 5.89 Desloratadine:3.44 (p=0.004) Gabapentin vs. Desloratadine: p=0.16 Quality of life: CRITICAL OUTCOME Not reported	Level of evidence: high risk of bias • Unclear randomisation method and allocation concealment • Open-label study • 3 exclusions after randomisation
Solak 2012	• Design: Randomized crossover trial • Funding/CoI: One author received a grant ERA-EDTA/ further no CoI • Setting: Turkey • Sample size: N=50 • Duration: 14 weeks	• Eligibility criteria: maintenance haemodialysis patients with neuropathy and/or neuropathic pain; 72,5% had pruritus • *A priori* patient characteristics: intervention vs. control ○ Age mean: 58.2 years ○ Male 30% ○ diabetic 38%	Gabapentin vs. Pregabalin	Pruritus: CRITICAL OUTCOME Pruritus VAS Score: Gabapentin: before 5.84 +/- 1.38, after 1.43 +/- 2.0 (p<0.001) Pregabalin: before 5.8 +/- 1.4, after 1.36 +/- 2.32 (p<0.001) Improvement in pruritus VAS-score: gabapentin: -4.41 +/- 1.78 (77.9%) pregabalin : -4.43 +/- 2.1 (79.2%) (p=0.844) Quality of life: CRITICAL OUTCOME See Atalay 2013?	Level of evidence: high risk of bias • Unclear allocation concealment • Open-label study • 10 exclusions after randomisation
Razeghi 2009	• Design: Double-blind clinical trial • Funding/CoI: no CoI • Setting: 3 hemodialysis centers, Iran • Sample size: N=34 • Duration: 9 weeks	• Eligibility criteria: hemodialysis patients with ESRD suffering from pruritus • A priori patient characteristics: intervention vs. control ○ Age mean: 58.4years ○ Male 23% ○ Median dialysis duration: 50 months	Gabapentin vs. Placebo	Pruritus: CRITICAL OUTCOME Pruritus score (VAS): Baseline: 100 gabapentin: 6.44 +/- 8.46 (p < 0.001) wash-out: 15 +/- 11.27 (p < 0.001) placebo : 81.88 +/- 11.06 (p < 0.001) Quality of life: CRITICAL OUTCOME Not reported	Level of evidence: high risk of bias • Cross-over trial, but not in a randomized way • Double blinded • High drop-out rate, some due to adverse events