

# VRAAG 5E: Restless legs

## Systematic reviews

Study ID	Method	Patient characteristics	Intervention(s)	Results	Critical appraisal of review quality
Aurora 2012	<ul style="list-style-type: none"> <li>SR</li> <li>Funding/Col: no Col</li> <li>Search date: June 2011</li> <li>Databases: MEDLINE</li> <li>Study designs: RCTs</li> <li>N included studies: 126 (12 studies on dialysis/ ESRD patients)</li> </ul>	<ul style="list-style-type: none"> <li>Eligibility criteria: adults diagnosed with restless legs syndrome</li> </ul>	<p>Several treatments, both dopaminergic and others</p> <p>vs.</p> <p>Control</p>	<p><u>Restless legs symptoms</u>: CRITICAL OUTCOME no MA-results for dialysis/ESRD patients</p> <p><u>Quality of life</u>: CRITICAL OUTCOME no MA-results for dialysis/ESRD patients</p>	<ul style="list-style-type: none"> <li>Low quality: Medline only, no explicit reporting of quality appraisal, unclear if two reviewers were used</li> <li>Included RCTs: Thorp (2001), Micozkadioglu (2004), Sloand (2004), Pellecchia (2004), Miranda (2004), Sakkas (2008), Giannaki (2010), Trenkwalder (1995), Sandyk (1987), Walker (1996), Read (1981), Bennett (1994)</li> </ul>
De Oliveira 2010	<ul style="list-style-type: none"> <li>SR</li> <li>Funding/Col: nothing to disclose</li> <li>Search date: 31 January 2009</li> <li>Databases: Cochrane Library, Medline, Pubmed, Lilacs, Embase, Scielo.</li> <li>Study designs: Randomized/Quasi-randomized controlled trials</li> <li>N included studies: 6</li> </ul>	<ul style="list-style-type: none"> <li>Eligibility criteria: Patients with ESRD and RLS (N=111 patients)</li> <li>Patient characteristics: <ul style="list-style-type: none"> <li>Age mean: 55 years</li> <li>Male: 59%</li> </ul> </li> </ul>	<p>All therapy-treatments used for uremic RLS</p> <p>vs.</p> <p>Placebo, no intervention, other drugs</p>	<p><u>Restless legs symptoms</u>: CRITICAL OUTCOME no MA-results</p> <p><u>Quality of life</u>: CRITICAL OUTCOME no MA-results</p>	<ul style="list-style-type: none"> <li>Good quality review</li> <li>Included RCTs: Walker (1996), Trenkwalder (1995), Ausserwinkler (1989), Pieta (1998), Sloand (2004), Thorp (2001)</li> </ul>
Trenkwalder 2008	<ul style="list-style-type: none"> <li>SR</li> <li>Funding/Col: Several authors have relations to pharmaceutical companies</li> <li>Search date: until December 2006</li> <li>Databases: Medline, Pubmed, Embase, Cochrane Central Register of Controlled Trials</li> <li>Study designs: All studies</li> <li>N included studies: ?</li> </ul>	<ul style="list-style-type: none"> <li>Eligibility criteria: Patients with restless legs syndrome</li> </ul>	<p>Pharmaceutically based treatments for RLS</p>	<p><u>Restless legs symptoms</u>: CRITICAL OUTCOME no MA-results</p> <p><u>Quality of life</u>: CRITICAL OUTCOME no MA-results</p>	<ul style="list-style-type: none"> <li>Low quality: no explicit reporting of quality appraisal, unclear if two reviewers were used</li> <li>Included RCTs: Sloand (2004), Collado-Seidel (1999), Micozkadioglu (2004), Thorp (2001)</li> </ul>

## Primaire studies

Study ID	Method	Patient characteristics	Interventions	Results	Critical appraisal of study quality
Giannaki 2013	<ul style="list-style-type: none"> <li>Design: randomized controlled trial</li> <li>Funding/Col: no competing interests</li> <li>Setting: Hospital of Larissa, Greece</li> <li>Sample size: N=32</li> <li>Duration: 6 months</li> </ul>	<ul style="list-style-type: none"> <li>Eligibility criteria: hemodialysis patients with restless leg syndrome</li> <li>A priori patient characteristics: intervention vs. control                             <ul style="list-style-type: none"> <li>Age mean: 56years</li> <li>Male 69%</li> </ul> </li> </ul>	<p>Exercise training for 6 months (n=16)</p> <p>vs.</p> <p>Ropinirole 0.25 mg/d (n=8)</p> <p>vs.</p> <p>Placebo (n=8)</p>	<p><u>Restless legs symptoms</u>: CRITICAL OUTCOME</p> <p>IRLS:</p> <p>Exercise-Baseline: 25.14 +/-9.09 Exercise-6Months: 13.42+/-11.28</p> <p>Dopamine-Baseline: 24.14+/-5.55 Dopamine-6Months: 11.57+/-7.84</p> <p>Placebo-Baseline: 19.71+/-7.49 Placebo-6Months: 18.57+/-10.65</p> <p><u>Quality of life</u>: CRITICAL OUTCOME</p> <p>SF-36 MCS score:</p> <p>Exercise-Baseline: 61.1+/-22.0 Exercise-6Months: 70.4+/-18.7</p> <p>Dopamine-Baseline: 39.1+/-23.8 Dopamine-6Months: 63.0+/-17.0</p> <p>Placebo-Baseline: 68.1+/-19.1 Placebo-6Months: 65.0+/-21.9</p> <p>SF-36 PCS score:</p> <p>Exercise-Baseline: 64.9+/-18.6 Exercise-6Months: 76.4+/-15.6</p> <p>Dopamine-Baseline: 48.7+/-21.0 Dopamine-6Months: 68.8+/-19.2</p> <p>Placebo-Baseline: 64.4+/-22.5 Placebo-6Months: 70.5+/-26.5</p>	<p>Level of evidence: unclear risk of bias</p> <ul style="list-style-type: none"> <li>Randomization method and allocation concealment not described</li> <li>Double blinding for medication groups</li> <li>3 patients lost-to-follow-up, and not included in analysis (1 in each group)</li> </ul>
Razatian 2015	<ul style="list-style-type: none"> <li>Design: Randomized clinical trial</li> <li>Funding/Col: no Col</li> <li>Setting: Kermanshah University, Iran</li> <li>Sample size: N=82</li> <li>Duration: 4 weeks</li> </ul>	<ul style="list-style-type: none"> <li>Eligibility criteria: Hemodialysis patients with restless legs</li> <li>A priori patient characteristics: intervention vs. control                             <ul style="list-style-type: none"> <li>Age mean: 55.3 years</li> <li>Male 56 %</li> </ul> </li> </ul>	<p>Gabapentin (n=42)</p> <p>vs.</p> <p>Levodopa-c (n=40)</p>	<p><u>Restless legs symptoms</u>: CRITICAL OUTCOME</p> <p>Pre-IRLS</p> <p>Gabapentin: 27.8 +/- 4.6 Levodopa-c: 27.6 +/- 4.4</p> <p>Post-IRLS</p> <p>Gabapentin: 10.4 +/-5.7 Levodopa-c: 14.2 +/-7.6</p> <p><u>Quality of life</u>: CRITICAL OUTCOME Not reported</p>	<p>Level of evidence: unclear risk of bias</p> <ul style="list-style-type: none"> <li>Randomization method and allocation concealment not described</li> <li>5 drop-outs (2 and 3 respectively)</li> </ul>