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### **Efficacy of step-down versus step-up analgesics in patients with (sub)acute sciatica in primary care: protocol of a randomized controlled trial**

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**Background & Aim:** Sciatica is the most prevalent specific type of low back disorders seen by general practitioners. Treatment of patients with (sub)acute sciatica is for a large part aimed to stay active and return to daily activities. Adequate prescription of pain medication is an important condition. There are two prescription strategies: 1) immediate opioid pain medication, followed by a step-down approach; and 2) step-up approach; starting with paracetamol (step 1), if necessary adding a NSAID (2), tramadol (3), morphine (4). This trial will assess the (cost-)effectiveness of immediate opioid prescription (step-down) compared with the current Dutch clinical guidelines' step-up approach, over a period of 6 and 12 weeks respectively.

**Methods:** The STEP-UP trial is a multi-center, open-label, randomized controlled trial in general practice with a 12 week follow-up. Patients aged 18-65 years with (sub)acute sciatica, severe radiating leg pain (NRS  $\geq 7$ ; range 0-10), duration of complaints <12 weeks and no current opioids usage are eligible to participate. Included patients are randomized in the two prescription strategy groups, and treated accordingly. Primary outcome is severity of radiating leg pain measured daily by 11-point NRS during 6 weeks follow-up. Secondary outcomes are among others: adverse reactions, quality of life, patient satisfaction, costs (direct medical and productivity costs), low back and leg pain severity, perceived recovery, treatment compliance, rescue medication usage, patient satisfaction and co-interventions. Outcomes are measured at baseline and at 3, 6, 9, and 12 weeks follow-up. Linear mixed model analyses with repeated measurements will be used to assess clinical differences between both groups. An economic evaluation will be performed using a cost-effectiveness analysis with severity of radiating leg pain and a cost-utility analysis with quality of life (QALY). Explorative subgroup analyses will be performed to identify possible effect modifiers.

**Results:** Currently recruiting eligible patients.

**Conclusions:** Expected in year 2019.