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The clinical and cost effectiveness of steroid injection compared with night splints for carpal tunnel syndrome: the INSTINCTS randomised clinical trial study protocol

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Abstract

Background: Patients diagnosed with idiopathic mild to moderate carpal tunnel syndrome (CTS) are usually managed in primary care and commonly treated with night splints and/or corticosteroid injection. The comparative effectiveness of these interventions has not been reliably established nor investigated in the medium and long term. The primary objective of this trial is to investigate whether corticosteroid injection is effective in reducing symptoms and improving hand function in mild to moderate CTS over 6 weeks when compared with night splints. Secondary objectives are to determine specified comparative clinical outcomes and cost effectiveness of corticosteroid injection over 6 and 24 months.

Method/Design: A multicentre, randomised, parallel group, clinical pragmatic trial will recruit 240 adults aged ≥18 years with mild to moderate CTS from GP Practices and Primary-Secondary Care Musculoskeletal Interface Clinics. Diagnosis will be by standardised clinical assessment. Participants will be randomised on an equal basis to receive either one injection of 20 mg Depo-Medrone or a night splint to be worn for 6 weeks. The primary outcome is the overall score of the Boston Carpal Tunnel Questionnaire (BCTQ) at 6 weeks. Secondary outcomes are the BCTQ symptom severity and function status subscales, symptom intensity, interrupted sleep, adherence to splinting, perceived benefit and satisfaction with treatment, work absence and reduction in work performance, EQ-5D-5L, referral to surgery and health utilisation costs. Participants will be assessed at baseline and followed up at 6 weeks, 6, 12 and 24 months. The primary analysis will use an intention to treat (ITT) approach and multiple imputation for missing data. The sample size was calculated to detect a 15 % greater improvement in the BTCQ overall score in the injection group compared to night-splinting at approximately 90 % power, 5 % two-tailed significance and allows for 15 % loss to follow-up.

Discussion: The trial makes an important contribution to the evidence base available to support effective conservative management of CTS in primary care. No previous trials have directly compared these treatments for CTS in primary care populations, reported on clinical effectiveness at more than 6 months nor compared cost effectiveness of the interventions.

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