UNDER Study

Ulnar Nerve Decompression Endoscopic Randomisation Study

A Prospective Randomised Controlled Trial Comparing Endoscopic Decompression of the Ulnar Nerve with Open Decompression in the Surgical Management of Cubital Tunnel Syndrome

Background:

Cubital Tunnel Syndrome (CuTS) is the second most common peripheral nerve compression neuropathy, affecting 6% of the population with 25 male and 19 female new cases per 100,000. Currently no consensus exists on the optimum method of surgical treatment. The UNDER Study seeks to compare Endoscopic Decompression with Open Decompression.

Open Decompression (OD) requires a longitudinal incision at the posteromedial elbow to expose the roof of the cubital tunnel. This enables release of compression points overlying the nerve under direct vision, however complications can include tethering of nerve to scar site resulting in new neuropathic pain and tingling in the hand/elbow and may also result in destabilisation of the ulnar nerve necessitating adjunctive procedures to prevent subluxation.

Endoscopic Decompression (ED) requires a shorter surgical incision in the skin overlying the cubital tunnel. Specially designed equipment is used to expose the nerve. A light source and camera are used with an endoscope that enables the nerve to be visualized along sites of potential compression, without having to incise all the overlying skin. Potentially this can result in a reduced risk of injury to smaller cutaneous nerves in the skin, reduced risk of destabilisation and quicker return to function. ED requires specific surgical training and as such poses additional risks of direct injury to the UN, incomplete decompression, and haematoma formation at the site of surgery and does not allow for adjunctive procedures if required.

Study Aim:
To ascertain the value and clinical efficacy of endoscopic and open cubital tunnel decompression

Primary Objective/Outcome Measure:
Ascertain relative patient reported clinical efficacy of endoscopic and open cubital tunnel decompression at 3 months as measured by the PRUNE score

Study Design:
Multicentre, Two Arm, Parallel Design, Superiority, Randomised Controlled Trial

Inclusion:

- Adults >=18 years or <80 years at time of surgery
- Clinical and neurophysiological diagnosis of CuTS
- Persistent CuTS after a 3-month trial of activity modification for mild severity cases
- Willing to accept study arm allocation
- Participants capable of giving informed consent and willingness to comply with protocol scheduled follow up visits

Exclusion Criteria:

- Patients with previous surgery for CuTS in the same limb
- Pre-operative subluxation at the elbow on clinical examination
- Clinical diagnosis of CuTS with normal neurophysiological studies

Outcome Measures:

- Prune Data
- Motor Function in the Ulnar Nerve Innervated Muscles measured by the BMRC Scale
- Scar Cosmesis using POSAS v2.0
- Return to Work
- Complications
- Quality of Life as measured by the EQ5D-5L

Phase 1:
30 Hand and Upper Limb surgeons from up to 20 centres will be invited to become investigators. They will be required to attend a cadaveric training workshop to learn the standardised endoscopic CuTS decompression.

Successful completion of this training will allow for progression to the pilot cohort evaluation phase of the study. Each investigator will be required to complete 5 successful endoscopic decompressions before becoming eligible for subsequent progression to Phase 2 of the trial. This will be determined by the satisfactory attainment of defined competencies and follow up outcome data captured at 6 weeks following operative intervention.

Phase 2:
This is the wider RCT whereby 334 eligible participants will be recruited at up to 20 hospitals and randomised to either Endoscopic or Open decompression with remote follow up to 6 months to capture the following:

Anticipated Study Timeline