# Study Plan – Outline

Aim: To assess for difference or non-inferiority of absorbable sutures vs non-absorbable sutures in open carpal tunnel release surgery

## Methods

PARTICIPANTS: Patients diagnosed clinically with carpal tunnel syndrome, with the use of nerve conduction studies required only in ambiguous cases. Exclude repeat operation same side, concurrent same hand operation, recent same hand operation within last 3 months, allergy to suture material, allergy to local anaesthetic, allergy to standard dressing or those otherwise requiring a deviation from the standard treatment protocol.

CONSENT: Patients consented prior to operation -wither in clinic or pre-procedure.

BLINDING: Patients will not be told what suture type is being used (blinded). The surgeon cannot be blinded to the suture material used.

RADNOMISATION: Random number generator used to create a list. Second hand to be operated on will receive the opposite suture to the first.

INTERVENTION DETAILS: Patients all operated on by Mr Lynskey (single surgeon). All under local anaesthetic. All patients receive the same interrupted suture technique. All knots will be externalised (not internalised or left loose). All sutures will use the same type of needle (size, shape, cutting edge). Same calibre of suture used (eg 3/0 or 4/0)

MEASUREMENTS:

Preoperative Data Collection:

* Patients complete Boston Carpal Tunnel Questionnaire + Boston FSC Score
* Handedness
* ASA Score
* Patient factors recorded including:
	+ BMI
	+ Diabetic
	+ Smoker
	+ Inflammatory arthropathy
	+ Immunosuppression
	+ Previous carpal tunnel steroid injection on side of operation
* Documentation of results of nerve conduction studies if performed.

Postoperative Data Collection (2 Weeks):

Prior to dressing removal

* Visual Analogue Scale (VAS) score for wound pain (1 – 10)
* BCTQ + BFSC

After Dressing removal

* ASEPSIS wound score.
* Any complications at 2 weeks recorded.

Postoperative Data Collection (6 Weeks):

* VAS Score for wound pain
* BCTQ + FSC
* Patient and Observer Scar Assessment Scale v2.0 (POSAS) for scar satisfaction
* If patient has now had both sides operated on – which side did they prefer and why.
* Any complications at 6 weeks recorded.

DATA ANALYSIS: We have hired a professional statistician to help with statistical analysis.

DATA STORAGE: Data will be stored on hospital servers and only transmitted via secure hospital systems. Data will be stored with NHIs attached for the purposes of analysis of comorbidities. Once the study is published at data will be available with trial number only attached to anonymise it