Platelet Rich Plasma For Acute Achilles Tendon Rupture: Two-Year Follow-Up Of The PATH-2 Randomised, Placebo-Controlled, Superiority Trial

Trauma / Foot & Ankle Trauma / Surgical Treatment

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Background

The PATH-2 trial found no evidence of a benefit of Platelet Rich Plasma (PRP) injection versus a placebo after Achilles tendon rupture (ATR) at six-months. ATR often leave longer term functional deficiencies beyond six-months. PATH-2 is a randomised multi-centre two-arm parallel-group, participant- and assessor-blinded, superiority trial.

Objectives

This study aim is to determine if PRP affect tendon functional outcomes at two-years after rupture.

Study Design & Methods

Adults with acute ATR managed with non-surgical treatment were recruited in 19 UK hospitals from 2015 to 2019. Exclusions were insertion or musculotendinous injuries, leg injury or deformity, diabetes, haematological disorder, systemic corticosteroids and anticoagulation therapy. Participants were randomised via a central online system 1:1 to PRP or placebo. Primary outcome was Achilles Tendon Rupture Score (ATRS) at two-years. Secondary outcomes were pain, Patient-Specific Functional Scale (PSFS), SF-12 and re-rupture rate. Assessors were blinded. Intention-to-treat and Compliance Average Causal effects (CACE) analyses were carried out. Consistency of effects across subgroups age, BMI,

smoking and gender were assessed using Forest plots. Pearson's correlation was used to explore ATRS correlation with blood and growth factors.

Results

216/230 (94%) participants completed the 6-months follow-up were contacted. 182/216 (84%) completed the two-year follow-up. Participants were aged mean 46 (SD 13.0), 57 female/159 male. 96% received the allocated intervention. Two-years ATRS scores were 82.2 (SD 18.3) in the PRP group (n=85) and 83.8 (SD 16.0) in the placebo group (n=92). There was no evidence of a difference in the two-years ATRS (adjusted-mean difference -0.752 95%CI -5.523 to 4.020, p=0.757), or in any secondary outcome, and no re-rupture between at two-years. Neither PRP cellular or growth factors correlated with the two-year ATRS.

Conclusions

PRP did not improve patient-reported function or quality of life two-years after acute Achilles tendon rupture, compared with placebo, indicating that PRP offers no patient benefit in the longer term.