Study Protocol

Official Title: Effect of Polydeoxyribonucleotide (PDRN) on Healing and Fatty Degeneration of Rotator Cuff in Human

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Background: Polydeoxyribonucleotde is a tissue regeneration activator. It binds adenosine A2A receptor and stimulate VEGF(vascular endothelial growth factor) synthesis and stimulate collagen synthesis. Nowadays, a lot of arthroscopic rotator cuff repairs are being performed. but the failure rate of rotator cuff repair is considerably high. Therefore, this study is to evaluate the effect of polydeoxyribonucleotide for healing and fatty degeneration of rotator cuff.

Objective: This study is to evaluate the effect of polydeoxyribonucleotide (PDRN) for healing and fatty degeneration of rotator cuff.

Methods: We will enroll 130 patients with rotator cuff tear who will undergo arthroscopic rotator cuff repair. 130 patients will be classified into two group. One group (PDRN) will be injected at the repaired cuff with 3cc polydeoxyribonucleotide just after surgery and be injected with another 3ml polydeoxyribonucleotide under ultrasound guidance 2 weeks after the surgery. The other group (CONTROL) will be injected with 3ml normal saline in the same manner.

Visual analog scale (VAS) of pain and other functional scores of the two group will be checked preoperatively and postoperative 3, 6, 12, 24 months. Growth factors (VEGF, FGF, IGF) will be checked preoperatively and postoperative 1h, 2 days, 2 weeks, 6 weeks, 3, 6 months. Follow up MRI will be checked at postoperative 6 months. The parameters will be compared using statistical analysis.

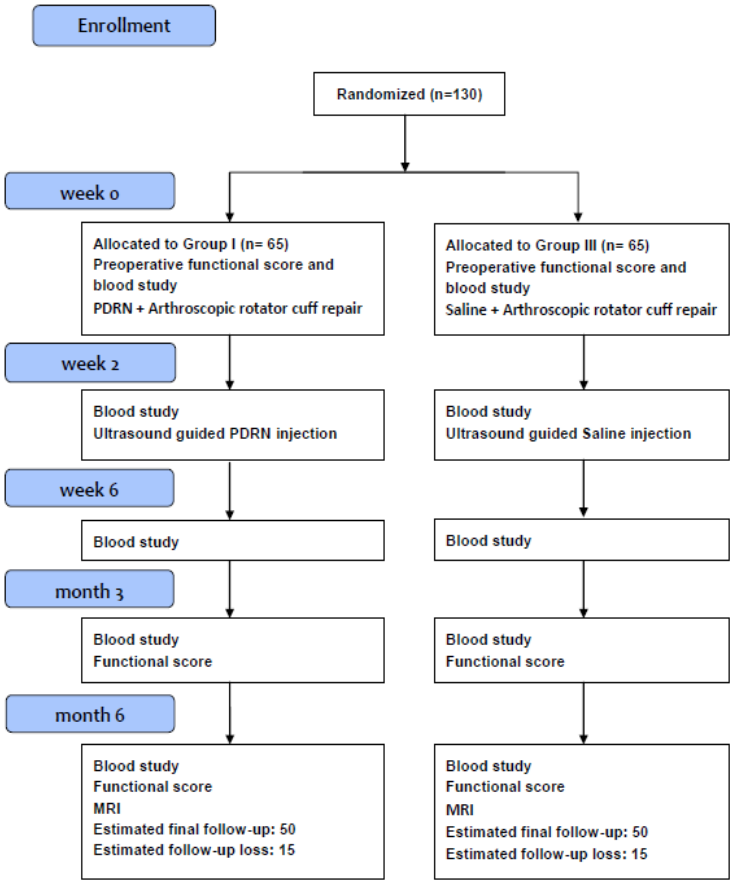

Fig 1. Flow diagram

Statistical analysis plan

In a previous similar study, prior power analysis was performed to determine the study sample size to provide a statistical power of 80% at an α level of .05. A sample size of 47 patients per group was calculated to be sufficient to detect a minimum 5-point difference in the Constant score at the end of 2 years with 10% probable loss of the data. We plan to follow up more than 50 participant in the each two groups. And we compared the score improvement sequentially between the two groups using Mann-Whitney test or independent t test according to the normality.