

GIHU004 – CONSORT 2010 Flow Diagram

**High Dose cohort**

0.8 mg pDNA

**Medium Dose cohort**

0.4 mg pDNA

**Low Dose cohort**

0.1 mg pDNA

Analysis

Enrollment

Allocation

Follow-Up

Assessed for eligibility (n=10)

Excluded (n=1)

  Not meeting inclusion criteria (n=1)

  Declined to participate (n=0)

  Other reasons (n=0)

Enrolled (n=9)

Allocated to intervention (n=3)

  Received allocated
intervention (n=3)

  Did not receive allocated
intervention (n=0)

Lost to follow-up (n=0)

Discontinued intervention (n=0)

Analysed (n=3)
 Excluded from analysis (n=0)

Allocated to intervention (n=3)

  Received allocated
intervention (n=3)

  Did not receive allocated
intervention (n=0)

Lost to follow-up (n=0)

Discontinued intervention (n=0)

Analysed (n=3)
 Excluded from analysis (n=0)

Analysed (n=3)
 Excluded from analysis (n=0)

Lost to follow-up (n=0)

Discontinued intervention (n=0)

Allocated to intervention (n=3)

  Received allocated
intervention (n=3)

  Did not receive allocated
intervention (n=0)