IRFLUVA: Improving the immune response to flu vaccine in older people

1. Participant Flow

A total of 84 individuals were assessed for eligibility, of whom 64 were enrolled and randomised at Baseline (Day 0). One participant was lost to follow-up between Baseline and Week 2, resulting in 63 participants completing all scheduled follow-up visits through Week 37 (Placebo: n = 32; Spermidine: n = 31).



Figure 1. CONSORT flow diagram showing participant progress through the IRFLUVA study visits from baseline (Day 0) to Week 37.

2. Baseline Demographic Characteristics

Parameter	Placebo (n = 32)	Spermidine (n = 31)
Sex, n (%)		
Female	22 (69%)	21 (68%)
Male	10 (31%)	10 (32%)
Age at vaccination (years)		
Median	71	71
Mean	70	71.2
Range	65–83	65–86
Ethnicity, n (%)		
White British	32 (100%)	30 (97%)

Parameter	Placebo (n = 32)	Spermidine (n = 31)
South East Asian	0 (0%)	1 (3%)
History of flu illness in past 6 months at Day 0, n (%)	0 (0%)	0 (0%)

3. Outcome Measures & Antibody Responses

Outcome Measure	Timepoints	Summary of Findings
Vaccine-Specific Serum IgG Antibody Response	Week 2, Week 13, Week 37	Seasonal influenza vaccination elicited a significant time-dependent serum IgG response characterised by acute post-vaccination elevation followed by expected physiological waning across all participants (p = 0.001).
Secondary & Exploratory Laboratory Outcomes	Baseline to Week 37	Laboratory analysis ongoing; data to be published in peer-reviewed manuscript.

4. Safety, Tolerability & Adverse Events

Study Period	Spermidine Group (n = 31)	Placebo Group (n = 32)
Weeks 0–2	**3 events:** Flatulence (Grade 1, mild); Constipation (Grade 1, mild); Indigestion (Grade 1, mild)	**4 events:** Constipation (Grade 1, mild); Indigestion (Grade 1, mild); Abdominal bloating (Grade 1, mild); Change to stool colour (Grade 1, mild)
Weeks 2–13	**2 events:** Flatulence (Grade 1, mild); Constipation (Grade 1, mild)	**3 events:** Abdominal bloating (Grade 1, mild); Constipation (Grade 2, moderate); Indigestion (Grade 1, mild)
Weeks 13–37	**0 events** (n/a)	**0 events** (n/a)

5. Data Availability & Conflicts of Interest

> **Publication Status:** Laboratory analysis ongoing; data to be published in peer-reviewed manuscript.

Conflicts of Interest: No conflicts of interest.