Across two sites, 72 subjects were enrolled and constitute the safety set. One participant was withdrawn from the investigation when a violation of one of the inclusion criteria was noted (VAS arm). Hence, 71 subjects (who received at least one study treatment) constituted the full analysis set. The study cohort was mainly female, between 42 and 65 years old.

**Figure 1: Participant Flow**

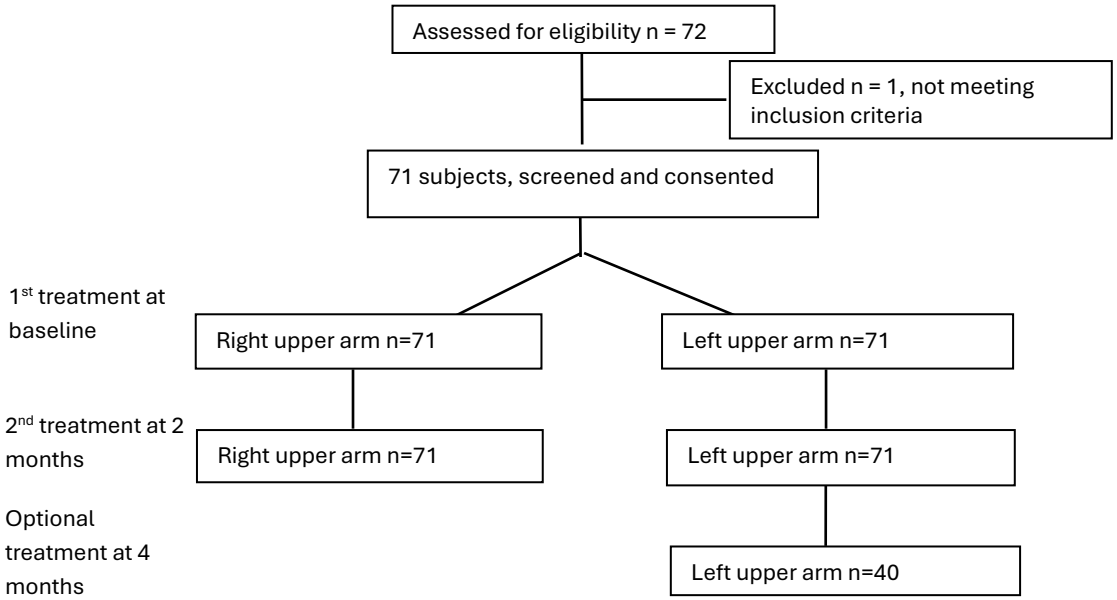


**Table 1: Participant's Baseline Characteristics**

| Item | Value (n=71) |
|---|---|
| sex (M: F) | 2.8%: 97.2% |
| Age (mean ± SD) [median] (years) | 53.2 ± 5.69 [53.0] |
| BMI (mean ± SD) [median] (kg/m$^2$) | 23.44 ± 2.92 [23.24] |
| Race | 98.6% Caucasian; 1.4% other |

The primary efficacy endpoint was 100%: At six months, 71/71 participants had a Global Aesthetic Improvement Scale (GAIS) score of ≥ 3 (“improved”, “much improved”, or “very much improved”) in right and/or left upper arms after treatment.

Secondary efficacy was shown in both independent evaluator assessments and subject assessments for up to 25 months after the primary treatment. Using the GAIS 66/71 (93.0%) and 68/71 (95.8%) of participants showed aesthetic improvement of their skin laxity at two and four months, respectively. At six months, treatment had led to improvement in all 71 participants (primary endpoint). At twelve months, there was a slight decline in the improvement rate (97.2%) from where there was a more pronounced decline to 85.7% and 82.9% at 18 and 25 months, respectively (**Table 2**).

**Table 2: Number and proportion of study participants with improvement, derived from evaluator GAIS assessments**

| **Timepoint** | **GAIS improvement: n/N (%) [95% CI]*** | | |
|---|---|---|---|
| | **Left upper arm** | **Right upper arm** | **Both upper arms** |
| Month 2 | n=66 (93.0%) [87.0-98.9%] | n=66 (93.0%) [87.0-98.9%] | n=66 (93.0%) [87.0-98.9%] |
| Month 4 | n=68 (95.8%) [91.1-100%] | n=68 (95.8%) [91.1-100%] | n=68 (95.8%) [91.1-100%] |
| Month 6 | n=71 (100%) [100-100%] | n=71 (100%) [100-100%] | n=71 (100%) [100-100%] |

| Timepoint | GAIS improvement: n/N (%) [95% CI]* | | |
|---|---|---|---|
| | Left upper arm | Right upper arm | Both upper arms |
| Month 12 | n=69 (97.2%) [93.3-100%] | n=69 (97.2%) [93.3-100%] | n=69 (97.2%) [93.3-100%] |
| Month 18 | n=60 (85.7%) [77.5-93.9%] | n=60 (85.7%) [77.5-93.9%] | n=60 (85.7%) [77.5-93.9%] |
| Month 25 | n=58 (82.9%) [74.0-91.7%] | n=58 (82.9%) [74.0-91.7%] | n=58 (82.9%) [74.0-91.7%] |

* totalling "improved", "much improved" and "very much improved"

The subjects' own assessment using GAIS score followed the similar pattern (**Table 3**).

**Table 3: Number and proportion of study participants with improvement, derived from GAIS self-assessments**

| Timepoint | GAIS improvement: n/N (%) [95% CI]* | | |
|---|---|---|---|
| | Left upper arm | Right upper arm | Both upper arms |
| Month 2 | n=63 (88.7%) [81.4-96.10%] | n=63 (88.7%) [81.4-96.10%] | n=63 (88.7%) [81.4-96.10%] |
| Month 4 | n=65 (91.5%) [85.1-98%] | n=65 (91.5%) [85.1-98%] | n=65 (91.5%) [85.1-98%] |
| Month 6 | n=68 (95.8%) [91.1-100%] | n=68 (95.8%) [91.1-100%] | n=68 (95.8%) [91.1-100%] |
| Month 12 | n=65 (91.5%) [85.1-98%] | n=65 (91.5%) [85.1-98%] | n=65 (91.5%) [85.1-98%] |
| Month 18 | n=58 (82.9%) [74.0-91.7%] | n=58 (82.9%) [74.0-91.7%] | n=58 (82.9%) [74.0-91.7%] |
| Month 25 | n=53 (75.7%) [65.7-85.8%] | n=53 (75.7%) [65.7-85.8%] | n=53 (75.7%) [65.7-85.8%] |

* totalling "improved", "much improved" and "very much improved"

Improvements in the satisfaction of subjects with their treatment outcomes regarding appearance, firmness, smoothness were found in more than 85% of subjects as early as 2 months, in at least 90% at 6 months, and remained high at the 25-month timepoint, namely in more than 78% of subjects (firmness) or more than 82% of subjects (measures of appearance and smoothness).

**Table 4: Subject Satisfaction Outcomes**

| Outcome | Month 2 | Month 4 | Month 6 | Month 12 | Month 18 | Month 25 |
|---|---|---|---|---|---|---|
| Overall appearance satisfaction | 90.10% | 90.10% | 94.40% | 91.50% | 88.60% | 87.50% |
| Inner arm appearance | 87% | 89% | 92% | 90% | 83% | 84% |
| Firmness | 88.70% | 90.10% | 90.10% | 87.30% | 84.30% | 78.60% |
| Smoothness | 87.30% | 90.10% | 90.10% | 91.50% | 87.10% | 84.30% |
| "I feel more attractive" | 85.90% | 90.10% | 94.40% | 94.40% | 81.40% | 82.90% |

The positive impact of aesthetic treatment on criteria of physical attraction was rapidly attained in the majority of subjects and sustained to a high degree over the entire study duration (77.1%- 84.3% across various descriptors).

Injection site reactions (redness, pain, tenderness, edema, bruising, pigmentation) were transitory and mainly mild when they occurred. Some were evaluated as adverse events.

In total, there were 65 adverse events in 27 participants. Three SAEs were recorded; they were not related to the procedure or device.

**Table 5: Summary of Safety Outcomes (SAE, AE)**

| Summary of Adverse Events | | |
|---|---|---|
| Category | Event Description | n (%) |
| Overall Adverse Events | Subjects experienced at least one adverse event | 27 (37.5%) |
| | Total number of AEs | 65 |
| | Serious Adverse Events (SAEs)* | 3 (4.2%) |

| | | |
|---|---|---|
| | SAEs related to treatment/device | 0 |
| | Adverse Device Effects | 0 |
| | Device Deficiencies | 0 |
| Injection site reactions evaluated as adverse events | | |
| SOC | Primary Term | n=72 |
| **General disorders and administration site conditions** | Injection site discomfort | 3 (4.2%) |
| | Injection site erythema | 3 (4.2%) |
| | Injection site haematoma | 4 (5.6%) |
| | Injection site mass | 1 (1.4%) |
| | Injection site oedema | 2 (2.8%) |
| | Injection site pain | 4 (5.6%) |
| | Injection site pruritus | 2 (2.8%) |
| | Nodule | 5 (6.9%) |
| | Pain | 1 (1.4%) |
| | Peripheral swelling | 1 (1.4%) |