Post-market Prospective Clinical Study of Nagor Perle Mammary Implants

NCT06013514

Status	RECRUITING
Sponsor	GC Aesthetics
Enrollment	60 participants

Key Eligibility Criteria

Inclusion (3)

- Genetic female subjects aged e18 and d65
- Subjects who underwent single or bilateral breast implantation with the study device for one of the following reasons:-
- i) Primary breast reconstruction following mastectomy (both for one-stage or two-stage surgeries, including patients with previous radiotherapy and who have ADMs of animal origin (bovine, porcine)). ii) Primary breast augmentation (cosmetic surgery) with or without mastopexy iii) Breast revision surgery with or without mastopexy c) Subjects who have received a Nagor PERLE implant. d) Subjects who have provided informed consent and can adhere to the requirements of follow up appointments as per the study protocol.

Exclusion (13)

- Subjects undergoing implant augmentation with a BMI \> 30 and undergoing reconstruction with a BMI \>32.
- Subjects with autoimmune disease, lung fibrocystic disease, conditions that interfere with wound healing and blood clotting, a weakened immune system, reduced blood supply to the breast tissue or any other condition for which breast implants are contraindicated.
- Subjects who have participated in a clinical study which involve chemical or drug study within 3 months prior to surgery, with the exception of subjects who are participating in breast cancer related clinical studies.
- Subjects with insufficient tissue covering due to either radiation damage on the chest wall, tight thoracic skin grafts or radical resection of the pectoralis major muscle.
- Subjects who have ADMs of synthetic origin.

... and 8 more (see full listing online)

Locations (1 total)

NHS Manchester, Manchester, United Kingdom, United Kingdom