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A post-market prospective clinical study of Nagor PERLE™ mammary implants

Submission date 23/08/2023	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 08/09/2023	**Overall study status** Ongoing	
Last Edited 04/06/2025	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
PERLE™ is a smooth round implant intended for breast augmentation or reconstruction and is approved for commercialisation. To assess the safety and performance of this implant the manufacturer Nagor is studying the rate of adverse events and satisfaction over a 10-year period.

Who can participate?
Women aged 18 to 65 years who underwent single or bilateral breast implantation

What does the study involve?
Follow-up visits will happen at specific points: 1, 3, 5, 8 and 10 years. Patients will fill in a quality of life survey. The research team will investigate any adverse events that have happened since the last follow-up. Surgeons will be asked about their satisfaction with the clinical outcomes.

What are the possible benefits and risks of participating?
No benefits are expected except for a better understanding of the breast implants' long-term safety. Expected risks of participating are minimal and only apply to data leaking as no additional interventions are expected except for standard practice.

Where is the study run from?
Manchester Private Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2022 to December 2035

Who is funding the study?
Nagor Ltd (UK)

Who is the main contact?
perle10pmcf@gcaesthetics.com

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
331001

ClinicalTrials.gov number
NCT06013514

Secondary identifying numbers
Protocol DM6 640 103, IRAS 331001, CPMS 58062

Study information

Scientific Title
A prospective, multi-center, observational, non-comparative, postmarketing surveillance study to obtain clinical outcome data on the Nagor PERLE™ range of silicone breast implants when used in breast augmentation or reconstruction for women from 18 to 65 years

Acronym
PERLE10PMCF

Study objectives
Observational study: assessment of safety and performance (rate of adverse event and satisfaction)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/10/2023, West of Scotland REC 4 (Research Ethics Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 (0)141 314 0213; WoSREC4@ggc.scot.nhs.uk), ref: 23/WS/0130

Study design
Prospective multi-center observational non-comparative unblind postmarketing surveillance study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Quality of life, Safety, Efficacy

Participant information sheet
Not available in web format, please contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Breast surgery: augmentation and reconstruction including revision for women

Interventions
Patients will have follow-up visits at 1, 3, 5, 8 and 10 years after breast surgery where they will assess their well-being by filling out a Breast-Q survey, and any adverse events are recorded with adverse event report forms. Surgeons will be asked for their feedback on the product (usage, clinical outcomes, satisfaction).

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Perle round, smooth breast implant

Primary outcome measure
Frequency and rate of capsular contracture of Baker grade III-IV and rupture at 1, 3, 5, 8 and 10 years using adverse event forms

Secondary outcome measures
1. Rate of the secondary surgical procedures required for correction of complications over a 10-year period following surgical implantation at any time during unscheduled follow-up using additional intervention form
2. Rate and frequency of local complications at 1, 3, 5, 8 and 10 years using adverse event reports
3. Perfomance associated with patient satisfaction at 1, 3, 5, 8 and 10 years using the Breast-Q method
4. Adverse effects observed at 1, 3, 5, 8 and 10 years using adverse event reports
5. Rate and frequency of any adverse events at 1, 3, 5, 8 and 10 years using adverse event reports

Overall study start date
01/08/2022

Completion date
31/12/2035

Eligibility

Key inclusion criteria
Current inclusion criteria as of 04/06/2025:

1. Genetic female subjects aged ≥18 and ≤65 years
2. Subjects who underwent single or bilateral breast implantation with the study device for one of the following reasons:
2.1. Primary breast reconstruction following mastectomy (both for one-stage or two-stage surgeries, including patients with previous radiotherapy and who have ADMs (bovine, porcine)) or synthetic meshes.
2.2. Primary breast augmentation (cosmetic surgery) with or without mastopexy
2.3. Breast revision surgery with or without mastopexy
3. Subjects who have received a Nagor PERLE implant.
4. Subjects who have provided informed consent and can adhere to the requirements of follow-up appointments as per the study protocol.

Previous inclusion criteria:

1. Genetic female subjects aged ≥18 and ≤65 years
2. Subjects who underwent single or bilateral breast implantation with the study device for one of the following reasons:
2.1. 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)).
2.2. Primary breast augmentation (cosmetic surgery) with or without mastopexy
2.3. Breast revision surgery with or without mastopexy
3. Subjects who have received a Nagor PERLE implant.
4. Subjects who have provided informed consent and can adhere to the requirements of follow-up appointments as per the study protocol.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Female

Target number of participants
700

Key exclusion criteria
Current exclusion criteria as of 04/06/2025:

1. Subjects undergoing implant augmentation with a BMI > 30
2. 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.
3. Subjects who have participated in a clinical study which involves chemical or drug study within 3 months prior to surgery, with the exception of subjects who are participating in breast cancer related clinical studies
4. 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
5. Subjects who, in the Investigator’s clinical opinion, have existing local or metastatic carcinoma of the breast that is unlikely to be fully excised at the time of insertion of the breast implant
6. Subjects with a known previous history of a sensitivity to silicone who, in the opinion of the Investigator, are unsuitable for surgery
7. Subjects with an active infection who are unsuitable for surgery unless, in the opinion of the investigator, they are treated and cleared by the investigator
8. Subjects with a history of abscesses anywhere in the body who, in the opinion of the Investigator, are unsuitable for surgery
9. Subjects with a known history of compromised wound healing

10. Subjects who, in the opinion of the Investigator, have an existing condition that would compromise their participation and follow-up in this study
11. Women who are pregnant and/or current breastfeeders who do not stop breastfeeding within 3 months of getting breast implants
12. Patients who have local recurrence or metastatic carcinoma at the time of insertion of breast implant

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Previous exclusion criteria:

1. Subjects undergoing implant augmentation with a BMI > 30 and undergoing reconstruction with a BMI >32
2. 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.
3. Subjects who have participated in a clinical study which involves chemical or drug study within 3 months prior to surgery, with the exception of subjects who are participating in breast cancer related clinical studies
4. 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
5. Subjects who have ADMs of synthetic origin
6. Subjects who, in the Investigator's clinical opinion, have existing local or metastatic carcinoma of the breast that is unlikely to be fully excised at the time of insertion of the breast implant
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12. Women who are pregnant and/or current breastfeeders who do not stop breastfeeding within 3 months of getting breast implants
13. Patients who have local recurrence or metastatic carcinoma at the time of insertion of breast implant

Date of first enrolment
01/05/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Central Manchester University Hospitals NHS Foundation Trust
Trust Headquarters, Cobbett House
Manchester Royal Infirmary
Oxford Road
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Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
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Study participating centre
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Portsmouth Road
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Sponsor information

Organisation
Nagor Ltd

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Sponsor type

Industry

Funder(s)

Funder type
Industry

Funder Name
Nagor Ltd

Results and Publications

Publication and dissemination plan
Planned publication

Intention to publish date
31/12/2036

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to intellectual property. White paper will shared take home message with additionnal data.

IPD sharing plan summary
Not expected to be made available