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Assessing how effective and safe poly-L-lactic acid microsphere injections are for treating male and female pattern hair loss

Submission date
26/11/2024

Recruitment status
No longer recruiting

Registration date
27/02/2025

Overall study status
Completed

Last Edited
27/02/2025

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Hair loss due to androgenetic alopecia (AGA) affects millions of men and women, impacting their confidence and quality of life. AGA is a condition where hair follicles shrink, leading to thinning hair and eventual hair loss. This study aims to evaluate the safety and effectiveness of Juläine, an injectable product containing poly-L-lactic acid (PLLA) microspheres, for promoting hair regrowth in individuals with AGA. The study will focus on measuring changes in hair density, hair shaft thickness, and participant satisfaction following treatment.

Who can participate?
Men and women aged 20 to 60 years who have been diagnosed with AGA can participate if their hair loss has been stable for at least six months

What does the study involve?
Eligible participants will attend six visits over 20 weeks at the study clinic. Each participant will receive three sessions of scalp injections with Juläine, spaced four weeks apart. The injections are reconstituted with saline and lidocaine to minimize discomfort. At follow-up visits, the study team will assess hair density using trichoscopy, take scalp photographs, and measure participant satisfaction through questionnaires. Participants will also receive aftercare instructions and have access to study staff for any concerns.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement in hair density and thickness, which could enhance their appearance and confidence. Although there is no guaranteed benefit, the results may contribute to improved treatments for hair loss in the future.

Possible risks include temporary redness, swelling, or mild discomfort at the injection site. In rare cases, small lumps (nodules) or other complications could develop. Participants will be closely monitored throughout the study, and the study team will be available to address any issues.

Where is the study run from?
Ouronyx Clinic, London, UK

When is the study starting and how long is it expected to run for?
September 2024 to August 2025. Recruitment will take place over several months, with each participant followed for 20 weeks.

Who is funding the study?
Nordberg Medical AB, the sponsor responsible for the development of Juläine

Who is the main contact?
Dr. Efthyvoulos Sokratous, Aesthetic Medicine Physician, Ouronyx Clinic, thivos.
sokratous@ouronyx.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Efthyvoulos Sokratous

Contact details
Ouronyx
20 St James's Street
London
United Kingdom
SW1A 1ES
+44 (0)7455007338
thivos.sokratous@ouronyx.com

Additional identifiers

Integrated Research Application System (IRAS)
352355

Study information

Scientific Title
Evaluation of the efficacy and safety of poly-L-lactic acid (PLLA) microspheres (Juläine) in the treatment of androgenetic alopecia: an open-label, investigator-initiated pilot study

Acronym
PLLA-AGA-Pilot

Study objectives
The primary hypothesis of this study is that Juläine (PLLA microspheres) is a safe and effective treatment for improving hair density and hair shaft thickness in patients with androgenetic alopecia (AGA) through its stimulatory effects on collagen synthesis and tissue remodeling. Specifically, it is hypothesized that Juläine will lead to a statistically significant increase in scalp

hair density and hair shaft thickness at 20-24 weeks compared to baseline measurements, without significant adverse events.

This hypothesis is grounded in the proposed mechanism of action of PLLA microspheres, which stimulate dermal fibroblasts to produce collagen, enhance tissue regeneration, and create an optimal microenvironment for hair follicle support and growth.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pending submission; 25/11/2025

Study design
Single-centre interventional open-label non-randomized pilot study with single-group assignment

Primary study design
Interventional

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Treatment of androgenetic alopecia in adult male and female patients experiencing hair thinning and loss due to this condition.

Interventions
Participants will be selected based on strict inclusion and exclusion criteria. Eligible participants will include men aged 20 to 60 years with androgenetic alopecia (AGA) classified as Norwood-Hamilton II-IV and women aged 20 to 60 years with AGA classified as Ludwig I-II. Hair loss must have been stable for at least six months, and participants must be generally healthy with no significant medical conditions. Written informed consent will be obtained after providing detailed study information. Exclusion criteria include other forms of alopecia, recent hair treatments, relevant allergies, specific medical conditions, pregnancy or lactation, psychiatric conditions, or inability to comply with study requirements.

During the screening visit, participants will undergo a thorough eligibility assessment, including a review of their medical history, scalp examination, and baseline assessments using trichoscopy and standardized scalp photography. Relevant laboratory tests, including a urine pregnancy test for women of childbearing potential, will also be conducted.

The study is an open-label, single-center, prospective interventional investigation with all participants receiving three sessions of intradermal scalp injections of Juläine, a poly-L-lactic acid (PLLA)-based medical device. Each treatment session involves reconstituting one vial of Juläine (containing 150 mg of PLLA) with 8 mL of sterile saline and 2 mL of 1% lidocaine. The injections will be administered evenly across the treatment area using mesotherapy techniques.

The intervention will occur over a total of nine weeks, with injections administered at baseline (Week 1), Week 5, and Week 9. Participants will be monitored on-site for 30 minutes post-injection to observe any immediate reactions, and they will receive detailed post-treatment instructions emphasizing the importance of scalp massage and signs of adverse events.

Follow-up visits will occur at Week 13 and Week 20 to assess both safety and efficacy. Trichoscopy, standardized scalp photography, the Dermatology Life Quality Index (DLQI), and participant satisfaction surveys will be used to measure outcomes. Adverse events will be systematically reviewed at all follow-up visits, and any unscheduled visits will be accommodated if participants report concerns or side effects.

This study aims to evaluate the efficacy and safety of Juläine in improving hair density and thickness in participants with androgenetic alopecia. There is no control arm, and no blinding is implemented, as all participants receive the investigational product. The methodology is designed to ensure participant safety and the collection of robust data on treatment outcomes.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Juläine (injectable poly-L-lactic acid microspheres)

Primary outcome(s)
Hair density improvement, measured using trichoscopy and standardized scalp photography, at baseline, Week 13 (Follow-Up Assessment), and Week 20 (Final Follow-Up)

Key secondary outcome(s))
1. Hair shaft thickness (μm) measured using trichoscopy at baseline, Week 5 (before the second treatment), Week 9 (before the third treatment), and Week 13 (four weeks after the final treatment)
2. Percentage of single follicular units measured using trichoscopy at baseline, Week 5, Week 9, and Week 13
3. Patient-reported quality of life measured using the Dermatology Life Quality Index (DLQI) at baseline, Week 13, and Week 20
4. Overall patient satisfaction with treatment measured using a 10-point Likert scale at Week 13 and Week 20
5. Adverse events monitored and recorded using standardized adverse event reporting forms continuously from baseline to Week 20

Completion date
31/08/2025

Eligibility

Key inclusion criteria
1. Male or female participants aged 20 to 60 years
2. Diagnosed with androgenetic alopecia (AGA):
2.1. Men with Norwood-Hamilton classification II-IV

2.2. Women with Ludwig classification I-II
3. Hair loss stabilized for at least 6 months prior to screening
4. Generally healthy with no significant medical conditions that could interfere with the study
5. Able and willing to provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 years

Upper age limit
60 years

Sex
All

Key exclusion criteria
1. Presence of other forms of alopecia (e.g., alopecia areata, scarring alopecia) or scalp infections
2. Skin diseases affecting the scalp
3. Use of pharmacological hair growth treatments (e.g., minoxidil, finasteride) or procedures (e.g., PRP therapy) within 6 months prior to screening
4. Known hypersensitivity to PLLA, lidocaine, or any components of Juläine
5. Autoimmune diseases or other medical conditions that could interfere with study outcomes (e.g., uncontrolled diabetes mellitus, active infections, or chronic inflammatory conditions)
6. Coagulation disorders or current use of anticoagulant therapy
7. Women who are pregnant, planning to become pregnant during the study period, or breastfeeding
8. Participation in another clinical trial within 3 months prior to screening
9. Psychiatric or psychological conditions that might compromise participation or affect the interpretation of results
10. Any condition or situation that, in the investigator’s opinion, may interfere with the participant’s ability to comply with the study requirements

Date of first enrolment
01/01/2025

Date of final enrolment
01/02/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Ouronyx
20 St James’s Street
London
United Kingdom
SW1A 1ES

Sponsor information

Organisation
Ouronyx

Organisation
Nordberg Medical

Funder(s)

Funder type
Industry

Funder Name
Nordberg Medical

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the study investigator by email to Dr. Efthyvoulos Sokratous, thivos.sokratous@ouronyx.com.
• Type of Data to be Shared: The anonymised datasets will include individual participant-level data collected during the study, including trichoscopy results, participant-reported outcomes (e.g., DLQI scores), and adverse event monitoring. Photographs of the scalp (with personal identifiers removed) used for efficacy assessments may also be shared in anonymised form.
• Timing of Data Availability: Data will be made available starting 12 months after the publication of the primary study results and will remain accessible for 5 years thereafter.
• Access Criteria: Data will be shared with academic researchers, clinicians, or other qualified

individuals for the purpose of advancing knowledge in androgenetic alopecia treatment or conducting meta-analyses. Requests must include a clear research proposal and evidence of ethical approval for the proposed secondary analysis.
• Mechanism of Data Sharing: Requests should be submitted via email to the corresponding investigator. Upon approval, the anonymised data will be shared securely via encrypted files.
• Ethical and Legal Restrictions: Participant data will be fully anonymised to ensure compliance with GDPR and other relevant data protection regulations. No personal identifiers will be included. All data-sharing agreements will include clauses to ensure that data is not used for commercial purposes without prior consent.
• Consent from Participants: Written informed consent will explicitly address data-sharing plans, including anonymised use of participant data for secondary research purposes.

IPD sharing plan summary

Available on request, Published as a supplement to the results publication