CASE STUDY

proderm
MEDICAL

ANDROGENETIC ALOPECIA

CONDUCT OF A FULL-SERVICE PHASE IIA MULTICENTRE STUDY WITH 200+ PATIENTS TO BE ENROLLED

proderm Medical was approached in autumn 2020 by a European Biotech company with a request to conduct a Phase IIa trial in patients suffering from androgenetic alopecia with a Hamilton-Norwood grade of 3V, 4, 5, 5A or 5V.

The following services were provided:

- Project Management
- Data Management
- Statistics
- Clinical & Medical Monitoring
- Site &Vendor Management
- Pharmacovigilance
- Scientific Writing

Study sites

The study was conducted at three sites in Germany. In addition to the proderm study site two external investigational sites were included.

Site 1
proderm clinical research unit, Schenefeld/Hamburg, Germany
No. of patients: 110

Site 2
Dermatological practice, Germany
No. of patients: 20

Site 3
University Hospital, Germany
No. of patients: 80

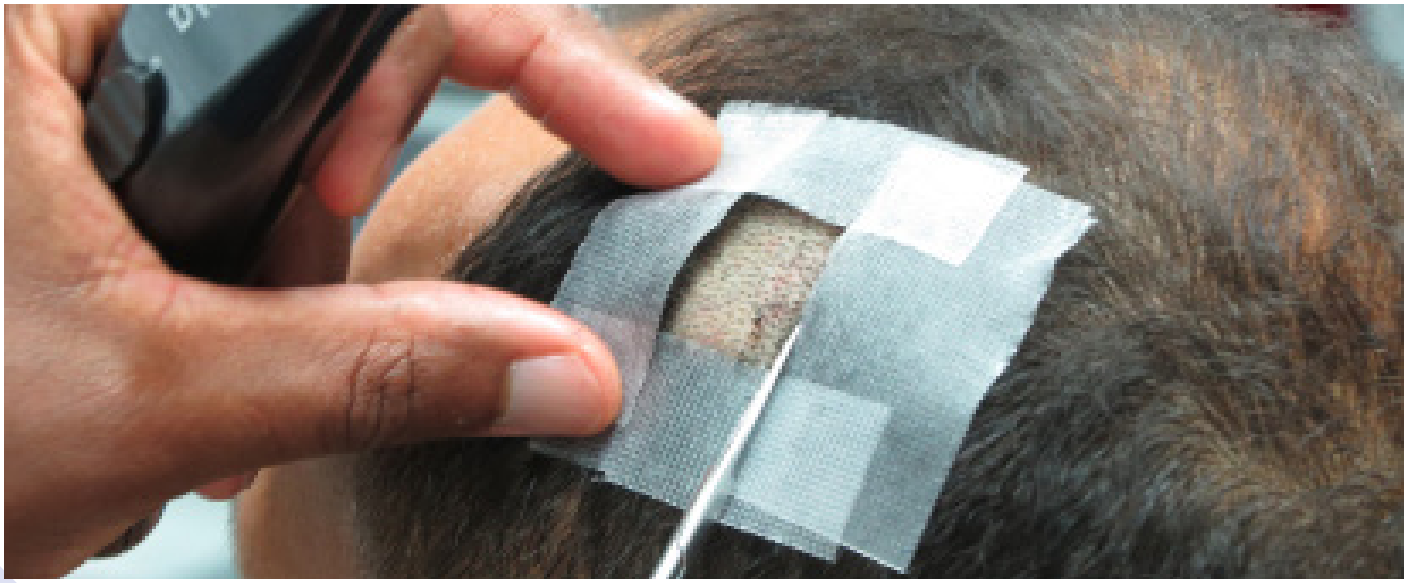
Study set up and analysis

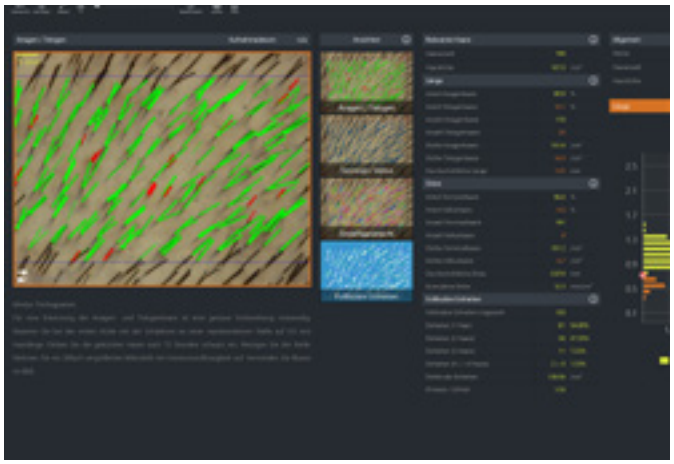
Hair growth measurements were done using the phototrichogram (PTG) method, the gold standard in hair treatment efficacy measurements. In this method, a scalp spot is selected and the hair is clipped to approximately 1 mm. After 48 hours, the hair is dyed and a high-resolution microscopic image is acquired. Hair growth parameters are assessed from those images.

Two enhancements developed by Tricholab were used to increase the precision of the results: Virtual Tattoo® and H2H-Matching®. Virtual Tattoo® helps to ensure that the exact same test spot is used in all examination. H2H Matching® enables individual hair tracking in the before-and-after images and determines if any of their parameters have changed.

Challenges

The main challenge with imaging based endpoints in multicenter studies is establishing and retaining uniform imaging quality. To achieve this, proderm implemented comprehensive and dedicated phototrichogram training units for the site staff. Our own PTG experts were available throughout the trial to ensure that questions and issues regarding the PTG method could be adequately addressed. Only one out of 210 patients had to be excluded from the PP population because of issues related to PTG data quality.





Androgenetic alopecia and the use of the PTG-method in the proderm clinical research unit: image generation, hair clipping and a screenshot of a trichogram investigation

Study milestones

6
weeks lead time

14
weeks enrollment period

28
weeks FPI to LPO

210
patients randomized

1
drop out

10
% screening failure rate

The milestones mentioned above become even more significant in the context of the pandemic.

Due to our tailor-made hygiene plan, only 9 out of 2730 visits (0.37%) had to be cancelled due to COVID-19. However, the postponement of the study due to the pandemic lead to tight recruitment deadlines as the expiry date of the IMP was approaching. Because of the quick inclusion of a third investigational site, our proderm team was able to meet the deadlines nonetheless. We were able to recruit 13 subjects per week over 16 weeks while maintaining excellent patient retention and study quality. There were no protocol violations regarding the in-/exclusion criteria, and only 14 subjects had to be excluded from the PP population due to major protocol deviations.

Sponsor feedback

„Fantastic - You have all made a great job making this possible and the number of drop outs are unprecedented low!“

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