Efficacy and safety of a novel plant-based exosome-like vesicle from Ashwagandha seed for improving hair growth parameters.

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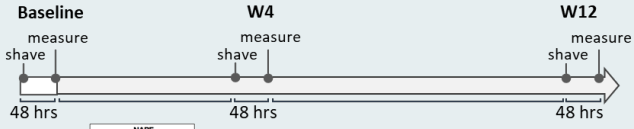
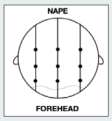
PURPOSE

Exosomes are currently being investigated for a range of regenerative therapies, including hair growth. Traditionally derived from human stem cells, their use is limited by sourcing and regulatory concerns. Recently, we described a new technology for isolating plant-derived exosome-like vesicles (PDEVs) from the Ashwagandha seed. Here, we evaluated the clinical efficacy and safety of this new technology.

STUDY DESIGN

- 20 male and female subjects were enrolled in a 12-week study.
- Ashwagandha PDEV- based serum was applied once a day for the duration of the study.
- A 0.5 in^2 micro-tattooed test site was shaved at baseline, weeks 4 and 12, then measured for change over 48 hrs.
- Subjects were blinded to the name of the test material.
- One-way ANOVA was used to compare objective measurements to baseline.
- Z test was used to compare subjective measurements.





Ash-PDEVs applied topically 1x/day as pictured + specifically on the shaved area

STUDY ENPOINTS

- Fotofinder® dermoscopy device utilizing TrichoScale Software
- Subjective Questionnaire
- Hair Pull Test
- Expert Grader Tolerance Evaluation
- Subjective Tolerance Grading Score

RESULTS

- 17 male and female subjects Fitzpatrick skin type I-V aged 26–55y completed the 12-week study. Of the three subjects who did not complete the study, 2 were lost to follow-up due to their absence from the tattoo visit, and 1 was disqualified for cutting his hair at week 12.
- Significant increases were seen in the total hair count and density, as well as anagen hair count and density at 12 weeks compared to baseline measurements.

Representative Fotofinder® image

Fig 1. Fotofinder image of target area at baseline and 12 weeks showing increased hair count.

Hair counts: Fotofinder® TrichoScale

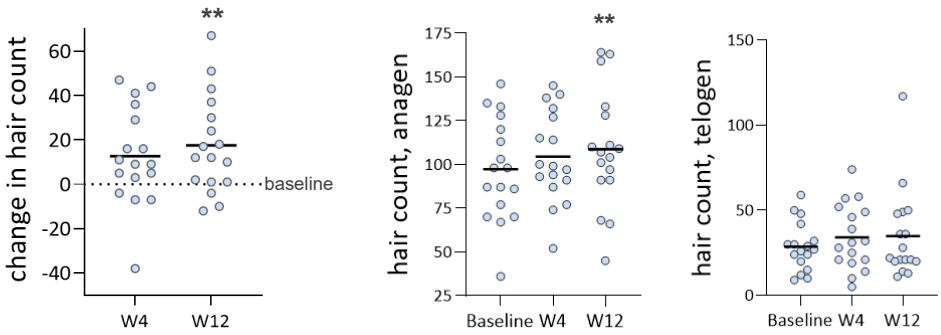


Fig 2. Significant increase of total and anagen hair counts and density, but not telogen hairs in target area by week 12.

Subjective Questionnaire

Responses to the subjective questionnaire indicated significant improvement in perceived hair growth and health with Ash-PDEV application at 12 weeks. Subjects reported significant improvement on the statements:

- **My overall hair quality has improved**
- **My hair looks healthier**
- **My hair feels stronger**
- **My hair is growing faster**

Hair pull test

All subjects had normal hair pull test results at baseline, week 4 and week 12, indicating that the Ash-PDEVs did not induce shedding over time.

Safety

Expert Grader Tolerance Score

No edema, eczematous injury, excoriation, or dryness was noted throughout the duration of the study.
Mild (score of 1 out of 3) erythema was noted in two subjects at baseline, three subjects at week four, and two subjects at week 12.

Subjective Tolerance Grading Score

No heating, stinging, or tugging was reported by the subjects throughout the duration of the study.

CONCLUSIONS

While plant-derived exosomes are still being researched for their potential in regenerative medicine, their efficacy and applications in humans is still unclear. Here we show that PDEVs from Ashwagandha seed show clinical improvements in hair growth and quality parameters that are perceived by 12 weeks of use, and that their use is well tolerated. Further research in a larger population is needed to confirm these results.

REFERENCES

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Dad, et al. Plant Exosome-like Nanovesicles: Emerging Therapeutics and Drug Delivery Nanoplatforms. *Molecular Therapy*, 2021.

CONFLICT OF INTEREST/DISCLOSURES: All authors are employed by Nutraceutical Wellness LLC.