A prospective, open label, multi-centre, observational, post-market study evaluating Juvéderm® Volift with Lidocaine for the correction of moderate to severe nasolabial folds (NLF)

Published: 30-08-2012
Last updated: 26-04-2024

The primary endpoint of this clinical investigation is to evaluate the impact of Juvéderm® Volift with Lidocaine treatment on the nasolabial fold severity as assessed by the Investigator using a NLF severity scale (NLFSS) at 12 months.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON37130

Source
ToetsingOnline

Brief title
VOLIFT

Condition

- Other condition

Synonym
dermal fillers, facial aging

Health condition

gezichtveroudering

Research involving
Human

Sponsors and support

Primary sponsor: Allergan Pharmaceuticals Ireland
Source(s) of monetary or material Support: Allergan Pharmaceuticals Ireland

Intervention

Keyword: Dermal Filler, Hyaluronic acid injection, Nasolabial Fold

Outcome measures

Primary outcome

The primary endpoint of this clinical investigation is to evaluate the impact

of Juvéderm® Volift with Lidocaine treatment on the nasolabial fold severity as

assessed by the Investigator using a NLF severity scale (NLFSS) at 12 months.

Secondary outcome

The secondary endpoints of this clinical investigation are:

• Investigator assessment of NLF severity at 1 and 9 months after treatment

using NLFSS

• Subject assessment of NLF severity at 1, 9 and 12 months after treatment

using NLFSS

• Subject satisfaction with aesthetic outcome

• Subject pain/swelling/bruising measurements

• Investigator satisfaction with aesthetic outcome

• Investigator ease of use (injection) measurements

• Reported Adverse Events and Serious Adverse Events (AEs/SAEs) and incidents

Study description

Background summary

Intrinsic and extrinsic aging manifests itself in the formation of wrinkles, folds, and lines, with the overall contour of the face dramatically changing. Deflation of soft tissue and wasting of areas (i.e., buccal fat pads, malar fat pads, perioral fat, chin, temporal fossa, and periorbital area) cause skin laxity, the formation of hollow contours, the deepening of folds, and reveals the bony structural elements of the face. Cheek depressions and the deepening of folds, such as the nasolabial folds (NLF) become more pronounced [1]. Yet because the root cause of volume loss is the decrease in cellular metabolism, the skin is unable to replenish itself.

Volume restoration of these areas could lead to smooth facial contours defined by high cheekbones, hollow jowls, and a defined jawline. Hyaluronic acid (HA) based gels have been successful in achieving these outcomes. Juvéderm® and Restylane® ranges have undergone several clinical studies, including randomized controlled studies for Juvéderm® in the US. Post-marketing assessments have also been conducted, and the published results revealed excellent satisfaction from patients and practitioners. Other clinical studies reported in the literature confirm the findings from the nonclinical studies. For the correction of moderate to severe NLFs, comparisons of HA containing dermal fillers versus other candidate dermal fillers have consistently shown greater effectiveness and duration of treatment with HA dermal fillers. Listed below are published clinical studies rating the performance of the Juvéderm family of products in amelioration of moderate to severe NLFs.

•In a 6-month pivotal trial, subjects received Juvéderm® Ultra, Juvéderm® Ultra Plus, or Juvéderm® Forma in one NLF and bovine collagen dermal filler, Zyplast®, in the other. Assessment of NLF severity was assessed every 6 weeks for 6 months using a 5-point NLF severity scale (Study JD-ZZ-001). At 6 months, all 3 Juvéderm® products yielded clinically significant improvement by at least 1 point from baseline compared to Zyplast, which only yielded 0.5 point improvement [2].
•Following the 6-month trial, subjects returned for an additional effectiveness assessment prior to a complimentary retreatment. Clinically significant reductions in NLF severity were observed at greater than 9 months post treatment with Juvéderm® Ultra and Juvéderm® Ultra Plus (75% and 81%, respectively), with 78% improvement in subjects treated with Juvéderm® Ultra Plus beyond 1 year [3].
•Further characterization of a subpopulation of subjects with baseline severe NLFs treated with Juvéderm® Ultra Plus was carried out for 1 year. At 24 weeks, 96% of subjects displayed clinically significant improvement compared to baseline, which was maintained 1 year post-treatment in 81% of subjects [4].

•The effectiveness of HA dermal fillers in the restoration of NLFs has been demonstrated across the Fitzpatrick skin types.2 Though Fitzpatrick skin phototypes IV, V, and VI are susceptible to hypertrophic or keloidal scarring and post inflammatory dyspigmentation, injection of Juvéderm® Ultra, Juvéderm® Ultra Plus, or Juvéderm® Forma did not lead to hypertrophic scarring, and there was no increased incidence of dyspigmentation in non-Caucasian versus Caucasian subjects. Further, 81%-89% of subjects had a clinically significant improvement in NLF severity scores at 24 weeks [5].

As with any dermal treatment injection, however, pain during administration is a possible side effect. Importantly, pain experienced during injection may compromise the physician*s ability to perform the procedure with precision. Physicians typically use pain-relieving agents concomitant with injection, such as a nerve block, topical anaesthesia, or a local anaesthetic. The inclusion of lidocaine in the HA formulation itself is intended to reduce the patient*s pain during the procedure and reduce or eliminate the need for additional pain relieving agents. As reviewed by Smith and Cockerham (2011), several studies have demonstrated significantly less pain associated with dermal fillers containing lidocaine, allowing for a quick treatment, reduced recovery time, and high patient satisfaction [6].

Juvéderm® Volift with Lidocaine, included in the Juvéderm® range of products, contains 17.5 mg/mL HA, crosslinked with 5.5% butane-diol-diglycidyl-ether (BDDE), and includes 0.3% lidocaine hydrochloride w/w. The technology platform, which Juvéderm® Volift with Lidocaine, Juvéderm® Volbella with Lidocaine, and Juvéderm® Voluma are manufactured by, results in highly cohesive HA-based products that provide higher lift capacity and resistance to deformation while exhibiting reduced susceptibility to enzymatic degradation [7,8]. Biocompatibility tests have confirmed Juvéderm® Volift with Lidocaine to be non-cytotoxic, non-irritant, no sensitising, non toxic, non carcinogenic, non-pyrogenic, and suitable for the intended purpose to be in contact with tissue/bone for more than 30 days. In vitro experiments comparing Juvéderm® Volift with Lidocaine to products of either similar composition or indication have demonstrated improved rheological and extrusion properties with increased resistance to free radical degradation [data on file]. Based on these pre-clinical data, it is expected that Juvéderm® Volift with Lidocaine will be safe and effective in treatment of moderate to severe NLFs and, specifically, that treatment will be accompanied by low levels of trauma and swelling, strong lift capacity, and sustained duration of effect

References

1.Kahn DM, Shaw RB. Overview of current thoughts on facial volume and aging. Facial Plast Sug. 2010; 26(5): 350-355

2.Baumann L, Shamban A, Lupo M, Monheit G, Thomas J, Murphy D, et al. Comparison of smooth gel hyaluronic acid dermal fillers with crosslinked bovine collagen: A multicenter, double-masked, randomized, within-subject study.

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4.Lupo M, Smith S, Thomas J, Murphy D, Beddingfield F. Cosmetic: Effectiveness of Juvederm Ultra Plus Dermal Filler in the Treatment of Severe Nasolabial Folds. Plastic and Reconstructive Surgery. 2008; 121(1): 289-297

5.Grimes PE, Thomas JA, Murphy DK. Safety and effectiveness of hyaluronic acid fillers in skin of color. J Cosmetic Dermatol 2009; 8: 162-168

6.Smith L and Cockerham K. Hyaluronic acid dermal fillers: can adjunctive lidocaine improve patient satisfaction without decreasing efficacy or duration? Patient Preference and Adherence 2011; 5: 133-139

7.Borrell M, Leslie DB, Tezel A. Lift capabilities of hyaluronic acid fillers. Journal of Cosmetic and Laser Therapy 2011; 13: 21-27.

8.Jones D, Tezel A, Borrell M. In Vitro Resistance to Degradation of Hyaluronic Acid Dermal Fillers by Ovine Testicular Hyaluronidase. Dermatol Surg. 2010; 36: 804-809.

Study objective

The primary endpoint of this clinical investigation is to evaluate the impact of Juvéderm® Volift with Lidocaine treatment on the nasolabial fold severity as assessed by the Investigator using a NLF severity scale (NLFSS) at 12 months.

Study design

This is a prospective, open label, multi-centre, observational, post-market study evaluating Juvéderm® Volift with Lidocaine treatment for the correction of moderate to severe nasolabial folds (NLF). Eligible subjects will undergo treatment with Juvéderm® Volift with Lidocaine in both NLFs. The Investigator will determine the appropriate volume to inject based on his/her clinical experience with the aim of achieving optimum correction. Juvéderm® Volift with Lidocaine will be injected according to the product*s Directions for Use (DFU) and the Investigator will complete a series of questions concerning the ease of use of the device. Fourteen days after the initial injection subjects will return to the clinic to answer questions on the safety and performance of the device. If the Investigator judges that optimum correction has not been achieved, an optional top-up injection is to be performed at this visit. Follow-up visits will occur at 1, 9, and 12 months after the last injection.

At all follow-up visits, the following assessments will take place:

• Investigator assessment of NLF severity using NLF severity scale (NLFSS)
• Subject assessment of NLF severity using NLFSS
• Investigator and subject satisfaction with aesthetic outcome measurement

Study burden and risks

The following risks are associated with treatment with injectable fillers in general and implantation of Juvéderm® Volift. They may occur immediately, but may be delayed. See also Directions for Use.

• Inflammatory reactions (redness, oedema, erythema, etc.) which may be associated with itching or pain on pressure or both, occurring after the injection. These reactions may last for a week. In particular, it has to be noticed that injection in the mucous membrane may cause more oedema and bruising due to the specific physiology of theses tissues. Besides, a preventive anti-inflammatory treatment by a medical practitioner can be recommended.
• Haematomas.
• Induration or nodules at the injection site.
• Staining or discolouration of the injection site.
• Poor effect or weak filling effect.
• Cases of necroses in the glabellar region, abscesses, granuloma and immediate or delayed hypersensitivity after hyaluronic acid and/or lidocaine injections have been reported. It is therefore advisable to take these potential risks into account.

Contacts

Public
Allergan Pharmaceuticals Ireland

Castlebar Road
Westport
IE
Scientific
Allergan Pharmaceuticals Ireland

Castlebar Road
Westport
IE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

•Male or Female 18 years of age or older
•Has 2 fully visible, approximately symmetrical NLFs, and has a severity scores of 2 or 3 on the 5-point photographic NLFSS (range 0-4) for both NLFs, as judged by the Investigator
•Have a reasonable expectation for their correction by injection via deep dermis, as described in this protocol
•Agree to refrain from undergoing other anti-wrinkle/volumizing treatments in the lower two-thirds of the face (below the orbital rim) for the duration of the study.
•Understand and be willing to follow all aspects of the study protocol and have signed and dated the Informed Consent prior to any study-related procedures being performed
•Being in good health as in the opinion of the Investigator

Exclusion criteria

•Has undergone cosmetic facial procedures [e.g., face-lift, or other surgeries] which may alter the appearance of the NLF area
•Cosmetic injections in the lower two-thirds of the face (below the orbital rim), within 6 months prior to entry in the study or be planning to undergo any of these procedures at any time during the study. NOTE: Prior treatment with HA fillers and/or collagen is allowed, provided the treatment was administered more than 6 months prior to study entry
•Has undergone volumizing of the mid/lower face within 9 months prior to study entry
•Has ever received semi-permanent fillers or permanent facial implants (e.g., calcium hydroxylapatite, poly-L-lactic acid, polymethylmethacrylate, silicone, expanded poly-tetrafluoroethylene) anywhere in the lower face (below the orbital rim), or be planning to be implanted with any of these products at any time during the study
•Have a history of anaphylaxis, multiple severe allergies, atopy, allergy to Lidocaine (or any amide-based anaesthetics), HA products, or Streptococcal protein, or be planning to undergo a desensitization therapy during the term of the study

•Be a pregnant female, lactating, or planning to become pregnant at any time during the study
•Be a female of childbearing potential not using a reliable means of contraception
•Have received any investigational product within 30 days prior to study enrolment or be planning to participate in another investigation during the course of this study
•Suffer from an uncontrolled personality disorder (e.g., body dysmorphia, depression)
•Have a history of or currently suffer from autoimmune disease (e.g., Rheumatoid arthritis, Crohn*s disease)
•Have a history of streptococcal disease (e.g., strep throat or rheumatic fever with or without heart complications)
•Have a history of skin cancer
•Suffer from Porphyria
•Have epilepsy which is not controlled by anti-epilepsy therapy
•Current cutaneous inflammatory and/or infectious processes (e.g., acne, herpes, etc.)
•Have a history of treatment with interferon
•Be on an ongoing regimen of anti-coagulation therapy (e.g., warfarin) or have taken non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., aspirin, ibuprofen) or other substances known to increase coagulation time (e.g., herbal supplements with garlic or ginkgo biloba) within 10 days of undergoing study device injection. NOTE: Study device injection may be delayed as necessary to accommodate this 10-day washout period
•Be on a concurrent regimen of high doses of Lidocaine (more than 400 mg) which may cause acute toxic reactions
•Be on a concurrent regimen of other local anaesthetics structurally related to amide-type local anaesthetics
•Have impaired cardiac conduction, severely impaired hepatic function, or severe renal dysfunction
•Have a condition or be in a situation that, in the Investigator*s opinion, may put the subject at significant risk, may confound the study results, or may interfere significantly with the subject*s participation in the study

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2012
Enrollment:	23
Type:	Anticipated

Medical products/devices used

Generic name:	Juvéderm® Volift with Lidocaine
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-08-2012
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	22-11-2012
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL40661.072.12