GLODERM 30L
CLINICAL EVALUATION

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Title of Study:

'To assess the safety and performance of Dermal Fillers (GLODERM 30L) in Patients with facial wrinkles.'

Objective: To Assess the safety and performance of GLODERM 30L in subjects with facial wrinkle improvement and incidence of all adverse events at 6months and any systemic adverse event.

Method:

- GLODERM 30L evaluation is designed as prospective, single center, single arm, open label evaluation .
- The evaluation device will be evaluated in the treatment of patients with wrinkle's assessing the Malar area, Marionette line, Perioral and Lip Area, Nasolabial folds assessment, Jaw line Assessment and evaluate the Full Face Global Aesthetic Improvement from day of treatment to follow up at 3 and 6 Months.

Eligibiltiy Criteria

Inclusion criteria :

- The patient must be ≥ 18 and ≤ 75 years of age.
- The patient must be willing to comply with the requirement of the Evaluation, including sequential photography or imaging for which copyright will be held by the Sponsor.
- The patient is willing and able to comply with the evaluation protocol.
- The patient is seeking soft tissue augmentation treatment on the face.
- The patient with folds, lines, wrinkles like Malar area, perioral line, Nasolabial fold, marionette Lines, jaw lines.
- The patient has a pre-treatment Wrinkle Severity Score (WSS) ≥ 2 for bilateral NLF to be treated
- The patient agrees to follow-up examinations out to 6 months post final treatment.

Eligibility Criteria

Exclusion Criteria

- At risk in term of precautions, warnings and contra-indication referred in the package insert of the evaluation devices,
- Who underwent previous injection of permanent filler in the injected area.
- Pregnant/lactating women
- Subjects who have an allergy to lidocaine, prilocaine or other amide-type anesthetic
- Had a chemical peel at the NLF area within 4 weeks prior to evaluation entry. In addition, subjects were restricted from undergoing chemical peels at the NLF area for the duration of the evaluation.
- Had any treatment with Botox® injections:
- in the upper 1/3 of the face within 2 weeks prior to entry into the evaluation, or
- in the lower 2/3 of the face within 24 weeks prior to entry. In addition, subjects were restricted from receiving Botox injections in the face for the duration of the evaluation.

Exclusion Criteria(Cont..)

- Had a history of hypo- or hyperpigmentation of the skin.
- Tolerance to antibiotics or corticosteroids.
- Had any infection, unhealed wound, or active inflammatory process (e.g., skin eruptions such as cysts, pimples, rashes, or hives) at the injection site(s).
- Immunocompromised/immunosuppressed (e.g., HIV-positive, transplant recipient, or presently receiving chemotherapy).
- A known history of keloids or bleeding disorders.
- Leukoderma (vitiligo) or a family history of leukoderma or other pigmentary disorders. Patient on Medication with blood thinners.
- Severe physical, neurological or mental disease.
- Excessive facial hair that might interfere with the evaluation of the wrinkle assessments.

Sample Size

- This is a single arm evaluation conducted with target of 34 subjects at single center treated with GLODERM 30L for face with Lines and wrinkles. Sample size of 34 subjects has been concluded based on the 92% power with 5% significance level and considering 10% drop-out rate.
- The entire subject participated in evaluation and treated with GLODERM 30L will be followed at 3 and 6 Months with assessment of Malar area severity, Marionette line, Perioral and Lip Area, Nasolabial fold, Jaw lines severity assessment and Global Aesthetic Improvement scale by using photograph at all the visits for comparison.

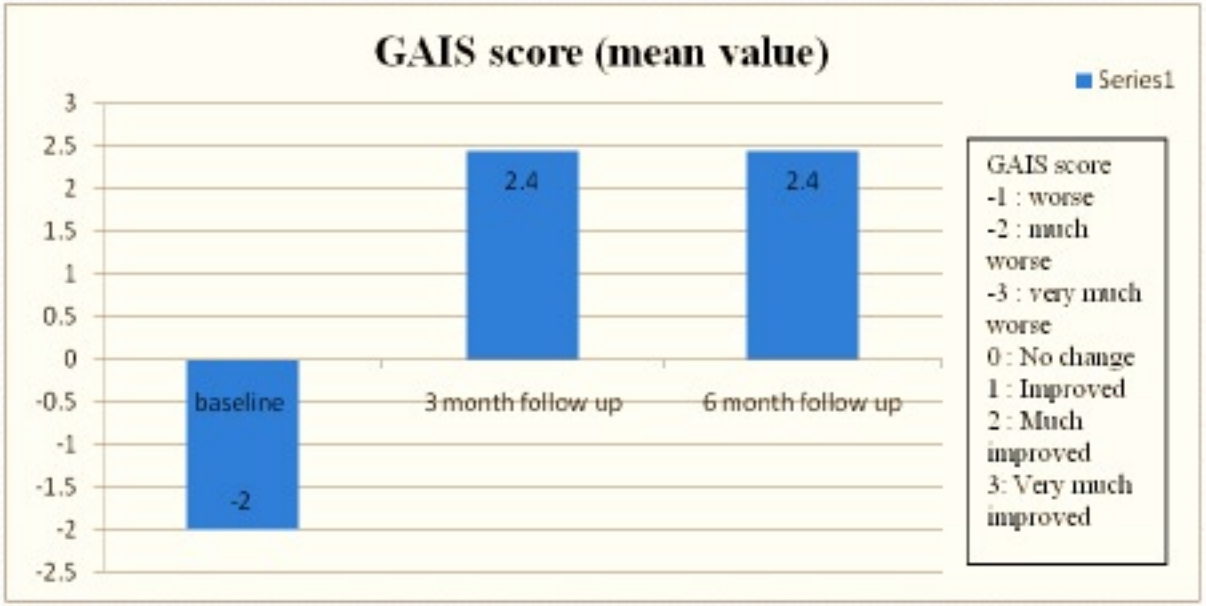
Study Schedule

Event	Screening/ Baseline	Procedure	Post –Procedure Day 0	FU 1 3 Months	FU 2 6 Months
Type of contact				Hospital Visit	Hospital Visit
Inclusion/ exclusion Criteria	X				
Physical examination	X				
Medical History	X				
Photograph	X		X	X	X
GAIS Assessment	X		X	X	X
Malar Area	X		X	X	X
Nasolabial fold assessment	X		X	X	X
Perioral and lip line area assessment	X		X	X	X
Marionette lines severity assessment	X		X	X	X
Jaw line severity assessment	X		X	X	X
Adverse Events and Serious Adverse Event Monitoring		X	X	X	X

Results

- **GLOBAL AESTHETIC IMPROVEMENT ASSESSMENT**

Visit	GAIS Score (mean value)
Baseline	-2
3 month follow up	2.4
6 month follow up	2.4



Full Face Global Aesthetic Score

Full Face Global Aesthetic Score	Baseline(%) N=18	3 Months(%) N=17	6 Months(%) N=17
Very Much worse	22.2	0	0
Much worse	55.6	0	0
Worse	22.2	0	0
Very much improved	0	44.4	44.4
Much Improved	0	50	55.6
Improved	0	5.6	0

Perioral and Lip Area: Barcode Lines Assessment

Score	Baseline(%) N=18	3 Months(%) N=17	6 Months(%) N=17
Deep Wrinkle, well define edges	38.9	23.5	23.5
Moderately deep wrinkle	22.2	17.6	17.6
Shallow Wrinkle	16.7	23.5	11.8
Just perceptible wrinkle	22.2	35.3	47.1

Perioral and Lip Area: Vermillion Border Assessment

Score	Baseline(%) N=18	3 Months(%) N=17	6 Months(%) N=17
Very Atrophic Lips	44.4	29.4	29.4
Less Atrophic Lips	44.4	23.5	23.5
Low Atrophic Lips	11.1	47.1	47.1

Score	Baseline(%) N=18	3 Months(%) N=17	6 Months(%) N=17
Clearly Defined	27.8	58.8	58.8
Medium Defined	50	35.3	29.4
Not Defined	22.2	5.9	5.9

Nasolabial Folds Assessment

Score	Baseline(%) N=18	3 Months(%) N=17	6 Months(%) N=17
Very deep wrinkle redundant fold	61.1	0	0
Deep Wrinkle, well define edges	38.9	23.5	17.6
Moderately deep wrinkle	0	35.3	41.2
Shallow Wrinkle	0	29.4	35.3
Just Perceptible wrinkle	0	11.8	5.9

Malar Area Assessment

Score	Baseline(%) N=18	3 Months(%) N=17	6 Months(%) N=17
Very deep wrinkle redundant fold	5.6	0	0
Deep Wrinkle, well define edges	11.1	0	0
Moderately deep wrinkle	16.7	17.6	11.8
Shallow Wrinkle	55.6	35.3	41.2
Just Perceptible wrinkle	5.6	47.1	47.1

MARIONETTE LINES SEVERITY ASSESSMENT

Score	Baseline(%) N=18	3 Months(%) N=17	6 Months(%) N=17
Very deep wrinkle redundant fold	50	0	0
Deep Wrinkle, well define edges	16.7	23.5	23.5
Moderately deep wrinkle	11.1	17.6	11.8
Shallow Wrinkle	22.2	23.5	29.4
Just Perceptible wrinkle	0	35.3	35.3

JAW LINE SEVERITY ASSESSMENT

Score	Baseline(%) N=18	3 Months(%) N=17	6 Months(%) N=17
Jaws Very Prominently visible	27.8	5.9	5.9
Jaws Prominently Visible	44.4	17.6	17.6
Jaws Slightly visible	27.8	52.9	47.1
No Jaws Visible	0	23.5	29.4

CONCLUSION

- GLODERM 30L is found safe and well tolerable.
- Results of present evaluation demonstrated significant improvement observed in GAIS score as well as in secondary efficacy parameters like Perioral and Lip Area, Nasolabial fold, Malar Area, Marionette lines severity and Jaw Line Severity at 3 and 6 months follow-up.
- An efficacy evaluation result of GLODERM 30L makes it suitable for use in patients with facial wrinkles.