Clinical Study Synopsis for Public Disclosure

These results are supplied for informational purposes only in the interest of scientific disclosure. The synopsis may include approved and non-approved uses, doses, formulations, treatment regimens and/or age groups. This information is not intended to substitute for informed medical advice. You should not use this information to diagnose or treat a health problem or disease without consulting with a Healthcare Professional. Before prescribing any product mentioned in this Register, Healthcare Professionals should always refer to the specific approved product labeling information in their country. The results from a single trial may not reflect the overall results and need to be considered in the context of the totality of the available clinical research results for a product.

Subjects' Satisfaction on Pan Facial Aesthetic Enhancement After Treatment With Azzalure® and the Restylane® Range (FIRST)

This study has been completed.

Sponsor:
Galderma

Information provided by (Responsible Party):
Galderma

ClinicalTrials.gov Identifier:
NCT01529203

First received: January 30, 2012
Last updated: September 16, 2014
Last verified: September 2014
History of Changes

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Results First Received: March 24, 2014

Study Type:	Interventional
Study Design:	Intervention Model: Single Group Assignment; Masking: Open Label
Condition:	Aging
Interventions:	Drug: Botulinum Toxin Type A (Azzalure) Device: Restylane ranges

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Azzalure and Restylane	All subjects will be injected with Azzalure and Restylane Botulinum Toxin Type A (Azzalure): Powder for solution for injection

	Restylane ranges: Hyaluronic acid (HA) 20 mg/mL + Lidocaine 0.3% (Restylane® Lidocaine, Restylane® Perlane™ Lidocaine, Restylane® SubQ Lidocaine, Restylane® Lip Volume, Restylane® Lip Refresh)

Participant Flow: Overall Study

	Azzalure and Restylane
STARTED	60
COMPLETED	57
NOT COMPLETED	3

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Azzalure and Restylane	All subjects will be injected with Azzalure and Restylane Botulinum Toxin Type A (Azzalure): Powder for solution for injection Restylane ranges: Hyaluronic acid (HA) 20 mg/mL + Lidocaine 0.3% (Restylane® Lidocaine, Restylane® Perlane™ Lidocaine, Restylane® SubQ Lidocaine, Restylane® Lip Volume, Restylane® Lip Refresh)

Baseline Measures

	Azzalure and Restylane
Number of Participants [units: participants]	60
Age [units: years] Mean (Standard Deviation)	47.6 (7.5)
Age [units: participants]	
<=18 years	0
Between 18 and 65 years	60
>=65 years	0
Gender [units: participants]	
Female	50
Male	10
Race (NIH/OMB) [units: participants]	
American Indian or Alaska Native	0
Asian	0

Native Hawaiian or Other Pacific Islander	0
Black or African American	0
White	60
More than one race	0
Unknown or Not Reported	0
Region of Enrollment [units: participants]	
France	20
Spain	20
United Kingdom	20

Outcome Measures

Show All Outcome Measures

1. Primary: Subject Satisfaction for the Full Face [Time Frame: Month 6]

Show Outcome Measure 1

2. Secondary: Global Aesthetic Improvement From Baseline [Time Frame: Week 3]

Show Outcome Measure 2

3. Secondary: Related Adverse Event [Time Frame: Month 6]

Show Outcome Measure 3

Serious Adverse Events

Show Serious Adverse Events

Other Adverse Events

Show Other Adverse Events

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.
There IS an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

- [x] The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is less than or equal to 60 days. The sponsor cannot require changes to the communication and cannot extend the embargo.
- [ ] The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is more than 60 days but less than or equal to 180 days. The sponsor cannot require changes to the communication and cannot extend the embargo.
- [ ] Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Results Point of Contact:

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No publications provided

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ClinicalTrials.gov Identifier:	NCT01529203 History of Changes
Other Study ID Numbers:	RD.03.SPR.29097
Study First Received:	January 30, 2012
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Health Authority:	Spain: Agencia Española de Medicamentos y Productos Sanitarios France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) United Kingdom: Medicines and Healthcare Products Regulatory Agency

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