Multi Country Study to Evaluate Patient Satisfaction for Non-Invasive Fat Reduction in Abdomen, Flanks, Upper Arms, Inner Thighs, Outer Thighs and Submental Area (NuCOOL)

Published: 11-11-2021
Last updated: 05-04-2024

To evaluate participant satisfaction and effectiveness of the CoolSculpting Elite System using CoolSculpting Elite applicators for non-invasive subcutaneous fat reduction of the abdomen and flanks, upper arms, inner thighs, outer thighs and...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51182

Source
ToetsingOnline

Brief title
MED-MA-PLS-0647

Condition

- Other condition

Synonym
Fat reduction

Health condition

Non-Invasive Fat Reduction

Research involving
Human

Sponsors and support

Primary sponsor: Allergan Aesthetics, an AbbVie Company
Source(s) of monetary or material Support: Industry

Intervention

Keyword: Non-Invasive Fat Reduction

Outcome measures

Primary outcome

The primary effectiveness endpoint is the proportion of participants with *satisfied* or *very satisfied* on the item 1 for the CSQ-Midsection, measured at Week 12 (Visit 8) for participants who receive 1 treatment session, or at Week 20 (Visit 9) for participants who receive 2 treatment sessions

Secondary outcome

* The proportion of participants who received treatment to abdomen and flank and one or more additional body areas for treatment with *satisfied* or *very satisfied* on CSQ-Overall Item 1 measured at Week 12 (Visit 8,12-week follow-up for participants who receive only 1 treatment session to all treated body areas) or at Week 20 (Visit 9, 12-week follow-up for participants who receive 2 treatment sessions to any or all treated body areas).
* The proportion of participants with *satisfied* or *very satisfied* on individual treated body area (upper arms, inner thighs, outer thighs, fat under chin) CSQ Item 1 measured at Week 12 (Visit 8, 12-week follow-up for participants who receive only 1 treatment session) or at Week 20 (Visit 9,12-week follow-up for participants who receive 2 treatment sessions) for the

respective treated body areas.

* Correct identification of baseline vs 12-week post-final treatment images of

the treated body area(s) by at least two out of three blinded, independent

reviewers for the following body areas:

o Midsection

o Upper arms

o Inner thighs

o Outer thighs

o Submental area

Success will be defined as at least 70% correct identification of the

pre-treatment images.

Study description

Background summary

CoolSculpting is a noninvasive, clinically proven fat-reduction treatment that selectively targets adipocytes using a patented cooling technology. The CoolSculpting mechanism of action is based on cryolipolysis, which works by cooling the subcutaneous tissue and preferentially targets adipocytes, leading to controlled elimination of adipocytes (Manstein 2008, Zelickson 2009). Adipose tissue appears more preferentially sensitive to cold injury than skin and other tissues (eg, skin, muscle, and nerve) and the crystallization of cytoplasmic lipids in adipocytes occurs at temperatures well above the freezing point of water (Epstein 1970, Beacham 1980, Manstein 2008).
While the CoolSculpting procedure is successful in reducing subcutaneous fat in various anatomical areas, patients often desire treatment in multiple body areas and typically more than one treatment session may be necessary to achieve desired results. Retrospective chart reviews indicate patients most commonly seek treatment for the abdomen and/or flanks and there is demand to treat other body areas beyond the midsection. In addition, physician feedback suggested that patients would prefer to have multiple CoolSculpting cycles performed at once in a single office visit to reduce the overall time of the procedures. The present study is intended to be reflective of real-world treatment

consultations where one or more body areas can be considered for treatment. In addition, capabilities of the device to allow for simultaneous use of applicators would allow for treatment of multiple body areas in the same or reduced treatment time.
Although there are numerous clinical studies that have been conducted with the prior CoolSculpting system, there have been a limited number of patients who have been studied with the CoolSculpting Elite device and applicators globally with treatment plans facilitating simultaneous applicator use and multiple body areas. There is a need to evaluate effectiveness, safety, and patient-centric outcomes related to the CoolSculpting Elite procedure as well as to generate data with the updated applicators across body areas.

Study objective

To evaluate participant satisfaction and effectiveness of the CoolSculpting Elite System using CoolSculpting Elite applicators for non-invasive subcutaneous fat reduction of the abdomen and flanks, upper arms, inner thighs, outer thighs and submental area.

To evaluate safety of the CoolSculpting Elite System using CoolSculpting Elite applicators for non-invasive subcutaneous fat reduction of the abdomen and flanks, upper arms, inner thighs, outer thighs and submental area.

Study design

This is a global, multicenter, multi-country, prospective, open-label, nonrandomized, interventional cohort, medical device post-marketing study evaluating the use of CoolSculpting Elite and CoolSculpting Elite applicators for noninvasive subcutaneous fat reduction of the abdomen, flanks, upper arms, inner thighs, outer thighs, and/or submental area in healthy volunteers.
Participants will be enrolled at approximately 9 study sites.
Participants are eligible to receive up to two treatment sessions separated 8 weeks apart for the body areas eligible for treatment. Assessments will be completed 12 weeks after the final treatment session.

Participant body areas selected for treatment during the study must be treated during the first treatment visit (Visit 2) and no new body areas may be treated at Visit 6. Participants planning to receive only one treatment session to a specific body area must have this treatment in Visit 2 during the first treatment session. Per investigator discretion, body areas identified for treatment may be treated simultaneously or sequentially. If sequential or simultaneous treatment is performed, there will be no difference in other treatment activities. Skin preparation, pain assessment, treatment site assessment, and post-massage, etc. will be identical in either case.
The study duration is up to approximately 20 weeks and consists of up to 7 scheduled study visits and 2 phone follow-ups per participant.

Intervention

Participants will undergo a CoolSculpting Elite treatment in an outpatient clinical setting. A treatment is comprised of timed segments of cooling (treatment cycle) followed by 2 minutes of manual massage. Treatments will be administered according to the CoolSculpting Elite user manual that has been prepared for specific countries and provided to the study sites. All device deficiencies (including malfunction and use error) shall be documented and reported by the investigator throughout the clinical investigation and appropriately managed by the sponsor.

Study burden and risks

There is no guarantee that participants will receive any benefits from their participation in this study. They may receive a cosmetic (aesthetic) benefit and the use of this non-invasive system may eliminate the need for an invasive procedure that requires anesthesia or recovery time to remove unwanted fat.

The treatment may cause side effects, which may be mild or serious. In some cases, these effects might be long lasting or permanent, and may even be life threatening. The risks and discomforts described below are related to receiving any CoolSculpting Elite study treatment:

Risks from device effects:
* Inflammation of the subcutaneous (under the skin) fat layer, which is a desired, expected and temporary effect of the procedure;
* Sensations of coldness, stinging, burning, pinching, pulling, or pressure associated with placement of the applicator and the initiation of the cold study treatment;
* Known skin effects (for example, blanching [skin becomes white or paler than usual]; erythema/redness, bruising, purpura or blood spots, petechiae (tiny red brown spots caused by bleeding into the skin), swelling, discomfort, tenderness, or soreness at the study treatment area, all mild to moderate in nature), which are temporary effects that resolve spontaneously shortly after the procedure; and
* Localized sensory changes (for example, numbness, tingling) at the study treatment area resolving within 12 weeks of the procedure.
Risks and discomforts that may potentially be experienced include:
* Severe bruising
* Prolonged bruising
* Severe erythema (skin redness)
* Prolonged erythema (skin redness)
* Severe swelling
* Prolonged swelling
* First degree burn
* Second degree burn

* Third degree burn
* Severe pain
* Cold-induced panniculitis (inflammation of the fatty layer under the skin)
* Skin pigment changes (change in skin color)
* Infection
* Discomfort during the procedure
* Discomfort after the procedure
* Prolonged sensory alteration (changes in sensation) after the procedure
* Sensory alteration (changes in sensation) requiring medical intervention
* Vasovagal symptoms (dizziness and fainting)
* Contour irregularity (lumpiness and unevenness of the skin)
* Allergic/irritant contact dermatitis (red, itchy rash due to an allergic reaction or irritation)
* Subcutaneous induration (hard nodules beneath the skin)
* Paradoxical adipose hyperplasia (enlargement and hardening of treated area)
* Hernia (fatty tissue may squeeze through a weak spot in the surrounding muscle or connective tissue)
* Treatment area demarcation (indentation from removing too much fat)

Contacts

Public
Allergan Aesthetics, an AbbVie Company

Dupont Drive 2525
Irvine CA 92612
US
Scientific
Allergan Aesthetics, an AbbVie Company

Dupont Drive 2525
Irvine CA 92612
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Participant must be in good health as determined by medical history, physical examination, vital signs, and investigator*s judgment, including no known active pandemic infection.
2. Participant (healthy volunteers) has read and signed the study written ICF.
3. Male or female participant 22 to 65 years of age inclusive at screening.
4. Participant has clearly visible and palpable fat in the abdomen and flanks, and participant may also be assessed for visible and palpable fat in one or more of the following body areas: left and right lower aspects of the upper arms, left and right inner thigh, left and right outer thigh, or submental area, which in the investigator*s opinion is appropriate for and may benefit from treatment.
5. Participant agrees to receive treatment of the abdomen and flanks (collectively, the midsection) and has option to receive treatment to at least 1 additional body area listed in criterion 4.
6. Participant has not had weight change fluctuations exceeding 5% of body weight in the preceding month.
7. Participant has a BMI of * 18.5 and < 30. BMI is defined as weight in kilograms divided by height in meters squared (kg/m2).
8. Participant agrees to maintain weight (ie, within 5% of body weight) by not making any changes in diet or exercise routine during the course of the study.
9. Participant agrees to have photographs taken of the treatment area(s) during the scheduled time periods

Exclusion criteria

1. Participant has a history of an invasive fat reduction procedure (eg, liposuction, surgery, lipolytic agents, etc) within or adjacent to the area being considered for treatment.
2. Participant has implants (eg, breast implants) in or immediately adjacent to the area of intended treatment.
3. Participant has a history of prior surgery or scar tissue related to the area being considered for treatment.
4. Participant has a known history of cryoglobulinemia, cold urticaria, cold agglutinin disease, or paroxysmal cold hemoglobinuria.
5. Participant has a known sensitivity to cold or has any condition with a known response to cold exposure that limits blood flow to the skin, such as cold urticaria, Raynaud*s disease, or chilblains (pernio).

6. Participant with a clinically significant bleeding disorder, or concomitant use of blood thinners, or is taking any medication that, in the investigator*s opinion, may significantly increase the participant*s risk of bruising or bleeding. Participant on low dose aspirin for medical condition is excluded if the medical history suggests significant risk of bruising or bleeding per investigator*s clinical judgement.
7. Participant has a history of carpal tunnel syndrome, compartment syndrome, or deep vein thrombosis in the upper or lower extremities (only applicable for participants receiving treatment to the upper arms or thighs).
8. Participant is currently taking or has taken diet pills or weight control supplements within the past 6 months.
9. Participant has any skin conditions, such as moderate to excessive skin laxity, open wound, or scars, and active infection, eczema, dermatitis or rashes in the location of the treatment sites that may interfere with the treatment or evaluation (stretch marks are not an exclusion).
10. Participant has an active implanted device such as a pacemaker, defibrillator, drug delivery system, or any other metal-containing implant, within or adjacent to the area being considered for treatment.
11. Participant (WOCBP) is pregnant or intending to become pregnant in the next 3 to 6 months and does not agree to use reliable contraception during the study.
12. Participant is lactating or has been lactating in the past 6 months.
13. Participant is unable or unwilling to comply with the study requirements.
14. Participant is currently enrolled in a clinical study of any unapproved investigational device, investigational product, or any other type of medical research judged not to be scientifically or medically compatible with this study.
15. Participant has any other condition or laboratory value that would, in the professional opinion of the investigator, potentially affect the participant*s response or the integrity of the data or would pose an unacceptable risk to the participant.
16. Participant has had a non-invasive fat reduction and/or body contouring procedure in the area(s) of intended treatment within the past 12 months.
17. Participant needs to administer, or has a known history of subcutaneous injections, into the area(s) of intended treatment (eg, cortisone, heparin, insulin) within the past 6 months.
18. Participant with known sensitivity or allergy to fructose, glycerin, isopropyl alcohol, or propylene glycol.
19. Participant has impaired peripheral circulation in the area to be treated.
20. Participant has neuropathic disorders such as post-herpetic neuralgia or diabetic neuropathy.
21. Participant has impaired skin sensation in or immediately adjacent to the treatment area(s).
22. Participant has a history of hernia in or immediately adjacent to the treatment area(s).
23. Participant diagnosed with a systemic fibrosing disease or fibrosis in the area intended or adjacent to the area to be treated.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	11
Type:	Anticipated

Medical products/devices used

Generic name:	CoolSculpting® Elite
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	11-11-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL77649.100.21