Post-market Clinical Investigation of High-Volume Anesthesia (Local Tumescent Anesthesia) used with the miraDry Treatment for Axillary Hyperhidrosis

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To collect safety and efficacy data from study participants that have been treated with the miraDry System using High Volume Anesthesia (HVA, also known as LTA or Local Tumescent Anesthesia) method as the local anesthesia delivery method.

Ethical review	Not approved
Status	Will not start
Health condition type	Epidermal and dermal conditions
Study type	Observational invasive

Summary

ID

NL-OMON51645

Source
ToetsingOnline

Brief title
miraDry Postmarket Tumescent Anesthesia Study

Condition

- Epidermal and dermal conditions
- Lifestyle issues
- Skin and subcutaneous tissue therapeutic procedures

Synonym
Underarm sweat

Research involving

Human

Sponsors and support

Primary sponsor: miraDry, Inc.
Source(s) of monetary or material Support: miraDry;Inc.

Intervention

Keyword: Axillary Hyperhidrosis, miraDry, Tumescent Anesthesia, Underarm Sweat

Outcome measures

Primary outcome

• Safety: Incidence of device and/or treatment related Serious Adverse Events (SAEs) through 30 days.

• Efficacy: Responder rate at 30 days, where a responder is defined as a study participant that reports a Hyperhidrosis Severity Scale (HDSS) score of 1 or 2.

Secondary outcome

• Incidence of device and/or treatment related SAEs through 6 months.

• Incidence of device and/or treatment related AEs through 6 months.

• Responder rate at 3 months and 6 months, where a responder is defined as a study participant that reports a HDSS score of 1 or 2.

• Change in quality of life (QoL) from baseline to 30 days, 3 months, and 6 months, as measured by the Dermatology Life Quality Index (DLQI).

• Change in odor assessment score from baseline to 30 days, 3 months, and 6 months.

• Satisfaction with reduction in odor at 30 days, 3 months, and 6 months.

• Reduction in axillary hair at 30 days, 3 months, and 6 months.

• Satisfaction with reduction in axillary hair at 30 days, 3 months, and 6

months.

Study description

Background summary

The miraDry System was FDA cleared in January 2011 (K103014) for the treatment of primary axillary hyperhidrosis, and over 350,000 treatments have been conducted world-wide. Publications on the use of the miraDry System technology to treat axillary hyperhidrosis have demonstrated long-term (12 month) efficacy for the treatment and safety.

The first commercial protocol for pre-treatment anesthesia was developed and used in clinical trials. It focused on infiltrated (injected) anesthesia (1% lidocaine with 1:100,000 epinephrine is recommended). The temporary template that is placed on the skin of the axilla indicates the recommended injection locations; between 20 and 60 injections with a fine needle required per axilla, depending on the size of the treatment area; resulting in anywhere from 12 to 25 cc*s of fluid injected per axilla. The anesthesia is injected into the subdermal area.

Many physicians using the miraDry System are using alternative methods for anesthetizing the axilla; the most common is infiltrative local tumescent anesthesia (LTA) at a high volume. miraDry often calls this method as High Volume Anesthesia (HVA) and the two terms are used interchangably. Tumescent anesthesia is commonly used for various dermatologic surgery procedures. This method involves using a larger volume of fluid with a lower concentration of lidocaine; the fluid is introduced under the skin through a few small injection sites and infiltrated into the desired region. For this application using the tumescent technique, between 100 and 300 cc*s of fluid per axilla would be introduced subcutaneously, depending on the size of the axilla.

This clinical trial will collect data on the safety and efficacy when High Volume Anesthesia is used as an alternate method of anesthetizing the axilla prior to the miraDry System being used. The investigators participating in this study are experts in the administration of tumescent anesthesia for dermatologic applications.

Study objective

To collect safety and efficacy data from study participants that have been treated with the miraDry System using High Volume Anesthesia (HVA, also known as LTA or Local Tumescent Anesthesia) method as the local anesthesia delivery

method.

Study design

a prospective, single-arm, open-label, multicenter study

Study burden and risks

As per the IFU, use of this CE-marked device has the following known potential risks:

* Swelling in the treated area
* Discomfort, tenderness or pain in the underarm when touched (treatable with non-prescription medications such as ibuprofen)
* Redness from the device suction
* Bruising at the numbing injection sites
* Bumps under the treated skin (can last for several months)
* Temporary altered sensation or tingling in small areas of the treated skin or upper arm (can last for several months)
* Partial underarm hair loss (may be long-lasting)

Other less common side effects include the following:
* Swelling in the adjacent arm or torso (usually lasting a few days)
* Hyperpigmentation (darkening of skin) in the treatment area
* Soreness in the shoulders or arms due to procedure positioning of the arms during the procedure
* Numbness or tingling in the arm due to the anesthesia (usually lasting less than 24 hours)
* Shaking due to epinephrine in the anesthesia (usually lasting less than 24 hours)
* Tight band in the underarm (gradually resolves)

There have been rare reports of the following:
* Altered sweating elsewhere on the body
* Small blisters/ulcerations or rashes in the treatment area
* Temporary altered sensation or tingling in the forearm or fingers (can last for several months)
* Weakness in the arm or fingers that gradually goes away (but can last for several months)
* Pain in the arm or fingers that gradually goes away (can last for several months)
* Pain in the underarm requiring prescription medications
* Infection/abscess in the treatment area
* Burns (first, second, or third degree are possible)

There are no additional risks to the patient through participation in this

study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion Criteria. Candidates for this study must meet ALL of the following criteria:
a) Adults (aged >=18 years) at time of consent.
b) A HDSS score of 3 or 4.
c) Excess sweating evidenced by at least two of the following:
a. Impairs daily activities
b. Frequency of at least one episode per week
c. Age of onset less than 25 years old
d. Positive family history

e. Cessation of focal sweating during sleep
d) In the opinion of the physician, treatment with the miraDry System is technically feasible and clinically indicated.
e) Willing and able to comply with protocol requirements and all study visits.
f) Female patients of child-bearing potential must not be pregnant or lactating and must agree to not become pregnant during the course of the study.

Exclusion criteria

Exclusion Criteria. Candidates will be excluded if ANY of the following conditions apply:
a) A cardiac pacemaker or cardiac defibrillator or other electronic implant.
b) Requires supplemental oxygen.
c) Known resistance to or history of intolerance of local anesthesia including lidocaine and epinephrine.
d) Secondary excess sweating due to medications, infections, malignancy.
e) Evidence of active infection.
f) Prior liposuction or other dissection surgery for axillary excess sweating.
g) Oral anticholinergic medication use (e.g., Glycopyrrolate) or cholinomimetic medication use within the last 4 weeks or planned use during the study*s follow-up phase.
h) Botulinum treatment of the axilla within the last 12 months.
i) Currently participating in or recently participated in another clinical trial (within the last 30 days).
j) History of or current neurologic deficit in the treatment area and/or limb.
k) History of cancer with the exception of (1) successfully treated basal cell or squamous cell carcinoma of the skin or (2) a history of successfully treated cancer that have been disease-free for five years.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Not approved

Date:	20-03-2023
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL81754.099.22