

Cover page for:

Research Subject Informed Consent Form

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**RESEARCH SUBJECT CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION**

Sponsor / Study Title: Allergan PLC / "SHAFFER WIDTH AND GIRTH: The Use of Injectable Fillers for Penile Enhancement"

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RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?

We expect that your taking part in this research will last one year.

Why is this research being done?

The purpose of this research is to examine the effectiveness of hyaluronic acid injectables, in this case, Juvéderm Injectable Gels by Allergan for the purpose of penile enhancement.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include:

1. You will receive several injections of Juvéderm injectable filler into your penis.
2. You and your sexual partner will be asked to fill out surveys that ask questions about your penis before and after study treatment.
3. Photos taken of your penis during this study will be released for publication and other potential research uses. More details on this are available in the photo consent document.
4. You will be asked to use a condom for at least 3 months following your final injections.

Could being in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include erythema (reddening of the skin), swelling, pain, infection, rash, bruising, and bleeding/formation of a hematoma in your penis. Most of these risks resolve on their own and are unlikely to lead to long term consequences. However, there is a very small risk that a “nodule” or permanent bump or change in shape may occur to your penis as a result of fibrosis. There is also a small risk that a part of the skin on your penis may die and need to be removed.

Additional less likely risks include:

- Inducement of Peyronie’s disease as a delayed consequence of the injected substance or of the injections themselves (scar tissue forming inside the penis. It can result in a bent, rather than straight, erect penis)
- Autoimmune side effects as can be rarely seen in the use of injectable products
- Blockage or constricting of the urethra from misplaced injections, that could lead to difficulty urinating
- Migration of injected material into the scrotal or perineal tissues
- Possible congenital malformations or other side effects related to the contamination of semen from injected material
- Priapism, which is a prolonged painful erection.
- Loss of sensation or change in sensation on your penis
- Changes in the nature of your erections
- Penile Rash
- Other penis disorders

Risks associated the phenylephrine (used to eliminate the artificially induced erection in this study) include:

- Exacerbation of angina, heart failure, or pulmonary arterial hypertension
- Peripheral and Visceral Ischemia
- Skin and Subcutaneous Necrosis
- Bradycardia or a low heart rate

You will also be taking a short course of steroids with the following potential side effects:

- Temporary Increase in Blood Glucose levels
- Temporary Increase in susceptibility to infections
- Changes in Appetite/Weight Gain
- Mood Disturbances
- Changes in Sleep patterns
- Swelling of your hands and feet
- Indigestion/Heartburn

Will being in this research benefit me?

You may benefit as a result of your participation in this study, there may be possible enlargement of your penis, But you may also not experience a benefit. Possible benefits to others include a better understanding of the efficacy of using Juvéderm for penile enhancement. Others will understand quantitatively how much they might expect to gain in penile length and girth from the procedures as well as any side effects that may be experienced from the procedure.

What other choices do I have besides taking part in this research?

Instead of being in this research, your choices include declining penile enhancement, or pursuing penile enhancement procedures outside of this study.

Summary Timeline of Study

	Injectons	Measurements	Photographs	Survey	Compensation
Initial Visit	x	x	x		
2 week follow-up	x	x	x	x	
6 week follow-up		x	x	x	
3 month follow-up		x	x	x	\$200
1 year follow-up		x	x	x	\$250

DETAILED RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

An investigator on this study is being paid by Allergan PLC, the company sponsoring this research study, for activities that are not part of the study. These activities may include, for instance, consulting, serving on advisory boards, or giving speeches. Please speak with your study doctor if you have questions about this.

Why is this research being done?

The purpose of this research is to better understand the use of Juvéderm Injectable Gels for the purpose of penile enhancement. Specifically this study looks at how length, and girth are impacted after the injection, as well as any potential side effects.

About 20 subjects will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last at a minimum 3 months, and at a maximum 12 months.

What happens to me if I agree to take part in this research?

During your initial visit, the length and girth of your penis will be measured. Three-dimensional photographs of your penis will also be taken. Following measurements and photographs, you will undergo injection of Alprostadil into your penis to achieve an erection. Repeat measurements of your penis will be taken at this time. Subsequently, Juvéderm Injectable Gels into your penis as seen fit by the study doctor. Your penis will then be returned to the flaccid state with the use of phenylephrine injections. Your penis will then be bandaged. Afterwards, you will go home and be asked to leave the bandage on for at least one day and massage the penis daily for a minimum of 15 minutes. You will also be given 6 days of steroid pills to take. You will also be asked not to engage in any form of sexual intercourse with your penis for a minimum of three days.

You will be asked to come in for a follow up visit in 2 weeks time . During this visit, you may or may not undergo another round of study treatment to achieve optimal results If you do, you will be asked to follow the same study treatment procedures you did following your initial visit, including taking steroids, daily penile massages, maintaining the bandage for a day, and refraining from sex for a day. During this 2 week visit you and your partner will also be asked to fill out a survey with questions regarding your study treatment. Measurements and photographs of your penis will also be taken at this time.

You will be required to follow up in another 4 weeks at the study doctor's office. During this time, you and your partner will again fill out a survey, and measurements of photographs of your penis will be taken. You will be asked to come for follow up at a date 3 months from the initial procedure as well as 12 months from the initial procedure, and during both of these visits you and your partner will again answer the survey. Your penis will again be measured and photographs will be taken.

The photos taken of your penis will be used to create a survey which will be placed on a survey platform, and be answered by 1000 individuals.

The use of Juvéderm Injectable Gels for penile enhancement is investigational, which means that it is not approved by the Food and Drug Administration (FDA). If you benefit from this study and are interested in additional treatments in the future, you may pursue treatment with Juvéderm Injectable Gels as desired.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be expected to:

You will be asked to follow the instructions you receive at each visit as described in the above sections. These include but are not limited to:

- You will be required to abstain from any form sexual intercourse using your penis in the 3 days following your study treatment(s).
- You will be asked to release photographs of your penis for others to view.
- If any complications should arise, or you have any concerns regarding your study treatment, you are asked to contact the study doctor . You may be asked to return to the office for evaluation and treatment.

Could being in this research hurt me?

The following are potential risks of your injections with Juvéderm:

- Pain and Swelling
- Bruising and Bleeding/formation of hematoma
- Infection
- Temporary decrease in sensation to the penis
- Formation of permanent nodules or penile contour irregularities as a result of fibrosis
- Potential permanent damage to skin of penis

Additional less likely risks include:

- Inducement of Peyronie's disease as a delayed consequence of the injected substance or of the injections themselves (scar tissue forming inside the penis. It can result in a bent, rather than straight, erect penis)
- Autoimmune side effects as can be rarely seen in the use of injectable products
- Blockage or constricting of the urethra from misplaced injections, that could lead to difficulty urinating
- Migration of injected material into the scrotal or perineal tissues
- Possible congenital malformations or other side effects related to the contamination of semen from injected material
- Priapism, which is a prolonged painful erection.
- Loss of sensation or change in sensation on your penis
- Changes in the nature of your erections
- Penile Rash
- Other penis disorders

You will also be taking a short course of steroids with the following potential side effects:

- Temporary increase in blood glucose levels
- Temporary increase in susceptibility to infections
- Changes in appetite/weight gain
- Mood disturbances
- Changes in sleep patterns
- Swelling of your hands and feet
- Indigestion/heartburn

All of these potential side effects are considered temporary and should go away after finishing the course of steroids.

Risks associated the phenylephrine (used to eliminate the artificially induced erection in this study) include:

- Exacerbation of angina, heart failure, or pulmonary arterial hypertension
- Peripheral and Visceral Ischemia
- Skin and Subcutaneous Necrosis
- Bradycardia or a low heart rate

Discomfort with questionnaires

Some people feel uncomfortable when answering questions about the quality of their life. Though it is always better to have fully completed questionnaires, you do not need to answer any questions that make you feel uncomfortable.

In addition to these risks, taking part in this research may harm you in unknown ways.

Will it cost me money to take part in this research?

There is no cost to you to participate in this study. In the unlikely event of a serious complication, you or your insurance may be responsible for covering the costs of your care. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Will being in this research benefit me?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include increased length and girth of your penis. Others may also benefit from your participation in this study as physicians will better understand if Juvéderm Injectable Gels enhance penis size.

What other choices do I have besides taking part in this research?

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- The Institutional Review Board (IRB) that reviewed this research

By participating in this study, you consent to and authorize the use and reproduction by the study doctor and affiliates, or anyone authorized by any of them, of any and all photographs, electronic images or video footage of you taken during this study. Such use shall include, but not be limited to research, advertising, publication, and public website usage. The Images (including any photographic negatives) shall be the sole property of the study doctor..

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Data collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

Whom to contact about this study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
Study Subject Adviser
Advarra IRB
6940 Columbia Gateway Drive, Suite 110
Columbia, MD 21046
- or call **toll free:** 877-992-4724
- or by **email:** adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser:
Pro00034295.

What if I am injured because of taking part in this research?

If you are injured or get sick because of being in this research, call the study doctor immediately. If this injury occurs during the daytime then you should call the daytime phone number, if it occurs outside of normal business hours then call the 24 hour available phone number. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment. You will be responsible for paying any charges that are not covered by insurance policy or the government.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- The research is canceled by the FDA or the sponsor
- You are unable to take the study drugs
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

Will I be paid for taking part in this research?

For taking part in this research, you may be paid up to a total of \$450 in credit for skin care services at the study doctor's plastic surgery office. Your compensation will be broken down as follows:

- If you successfully return for follow-up at the 3 month period you will receive \$200 in credit towards skin care services.
- If you successfully return for follow-up at the 12 month period you will receive another \$250 in credit towards skin care services.
- You will not receive any compensation for dropping out of this study.

Statement of Consent:

Your signature documents your consent to take part in this research.

Subject's Printed Name

Subject's Signature

Date

Printed Name of the Person Conducting the
Consent Discussion

Signature of the Person Conducting the
Consent Discussion

Date

Authorization To Use And Disclose Protected Health Information

If you decide to be in this study, the study doctor and research team will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the research team may share health data about you with authorized users. Authorized users may include:

- Representatives of the Sponsor
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this research, if applicable.
- A data safety monitoring board which oversees this research, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study injection works and is safe.
- To compare the study injection to other drugs
- For other research activities related to the study injection

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this,

you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

Statement of Authorization

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

Printed Name of Subject

Signature of Subject

Date

Printed Name of the Person Obtaining the Authorization

Signature of the Person Obtaining the
Authorization

Date