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An open label, pilot study to determine the effect of weekly injections of Invicorp on male Erectile Dysfunction (ED) following surgery to remove the prostate

Submission date
16/01/2023

Recruitment status
No longer recruiting

Registration date
10/02/2023

Overall study status
Completed

Last Edited
18/06/2024

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Prostate surgery, also known as a prostatectomy, is a procedure to remove all or part of the prostate gland. This surgery can have several consequences, both short-term and long-term. Short-term consequences can include pain and discomfort, bleeding, and the need for a catheter to assist with urination. There may also be sexual side effects, such as erectile dysfunction (difficulty getting or maintaining an erection) or decreased sexual desire.
Long-term consequences can include incontinence (inability to control urination) or bowel problems. There may also be ongoing sexual side effects, such as difficulty achieving orgasm or a decrease in the intensity of orgasms.
This study aims to understand how weekly injections of Invicorp affect the patient's ability to have and hold an erection.

Who can participate?
Men at least 18 years old who have recently undergone surgery where their prostate was removed because they had prostate cancer.

What does the study involve?
The duration for each patient is 4-5 months and they will attend the hospital approximately once per month. Invicorp will be injected at the hospital and the patient will complete questionnaires about sexual function and a device will measure any erection. The patient will then take the product home for use.

What are the possible benefits and risks of participating?
By taking part in this study and by using the study drug, you might be able to achieve a successful erection for intercourse. The information from this study may help us to treat erectile dysfunction post radical prostatectomy in the future.
You may experience an ache in the penis for a few hours after the injection. If there is failure of the injection to achieve an erection or any bleeding noted from the urethra this may be due to

the injection not being administered at the correct site. As with any drug, there may be side effects. Invicorp is an approved medicine in the UK and the common side effects (may affect up to 1 in 10 people) are flushing of the face and upper part of the body and bruises around the injection site.

Where is the study run from?
Nephro-Urology Clinical Trials, Fitzrovia Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2022 to June 2024

Who is funding the study?
RestoriT Ltd (UK)

Who is the main contact?
Dr Brian Leaker, brian.leaker@qasmc.com

Contact information

Type(s)
Scientific

Contact name
Prof Brian Leaker

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Additional identifiers

Clinical Trials Information System (CTIS)
2021-005456-11

Integrated Research Application System (IRAS)
310426

Protocol serial number
RestoriT-001

Study information

Scientific Title

An open label, pilot study to determine the effect of in-centre and at-home administration intra-cavernosal injections of Invicorp on male Erectile Dysfunction (ED) post radical prostatectomy

Study objectives
Rationale: The treatment of localized prostate cancer with surgery or radiotherapy is associated with a lower incidence of disease progression but a higher incidence of troublesome side effects, such as sexual dysfunction defined as an inability to sustain an erection sufficient for sexual intercourse. Most urologists recommend a PDE5-inhibitor such as oral sildenafil plus a vacuum erection device to be started within 3 months of surgery. Alternatively, and especially in men without bilateral nerve-sparing surgery, intra-cavernosal injections (ICI) alprostadil (Caverject) are recommended second line options and have been shown to be more effective than PDE5-inhibitors; however, ICI alprostadil has a 50% attrition rate due to penile pain at the injection site and patient aversion to self-injection. Invicorp is a combined formulation of VIP (Vasoactive Peptide Aviptadil 25mcg) and the alpha antagonist phentolamine (2mg) and is administered by ICI injection. Invicorp has been used successfully as rescue therapy in up to 60% of non-responders to Caverject. In this exploratory study the standard marketed formulation will be used to determine if Invicorp can reverse or partially reverse immediate erectile dysfunction following radical prostatectomy. The patient population will consist of patients who undergo radical prostatectomy with either nerve sparing or non-nerve sparing procedures and we will determine the responders in each population to ICI Invicorp.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/03/2022, London - London Bridge Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 207 1048 124; londonbridge.rec@hra.nhs.uk), ref: 22/LO/0048

Primary study design
Interventional

Study design
Open-label non-randomized study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Erectile Dysfunction (ED) post radical prostatectomy

Interventions
The study will require the subject to attend a Screening Visit within 4 weeks prior to the subjects scheduled radical Prostatectomy. The subject will then attend Visit 1 (Study Drug Administration Visit) 1-3 weeks post radical Prostatectomy. The subject will be provided study drug for up to twice weekly at-home dosing. Sexual function questionnaire (International Index of Erectile Function (IIEF) will be recorded at the in-centre visits (1, 2, 3 and 4) and post at-home dosing. Visit 2, 3 and 4 will occur at 4 weekly intervals post Visit 1 (+/-3 days) at the clinic. A follow up visit will occur 14 days post Visit 4(+/-7 days).

At the Screening Visit the subject will be assessed for eligibility as per the study inclusion /exclusion criteria. The subject will undergo a physical examination, vital signs, ECG and provide medical history. Blood samples will be performed (Haematology, Chemistry levels, presence of Hepatitis B, C and HIV). The subject will complete sexual function questionnaires.

During the study subjects will receive the standard post-operative penile rehabilitation as per University College of London guidelines excluding the use of PDEV inhibitors. Adverse Events and Concomitant Medications will be recorded. Visit 1 (Study Drug Administration Visit) will occur 1-3 weeks post radical prostatectomy. The subject will be re-assessed for eligibility for inclusion in the study and will undergo a physical examination, vital signs, an ECG, a COVID-19 PCR test and complete sexual function questionnaires. The subject will then be administered Invicorp 25mcg/2ml via intra-cavernosal injection. A Rigiscan will be performed approximately 15 minutes post dose. Adverse Events and Concomitant Medications will be recorded.

At Visit 1 subject will be trained to administer Invicorp with intracavenosal route by an experienced Physician in the matter. The subject will be dispensed the study drug along with Subject Diary Cards and IIEF questionnaires for at-home dosing and subsequent data collection. Subjects will be instructed to use Invicorp before anticipated sexual intercourse. Subjects will also be instructed that Invicorp injections must not be used more than once per day and no more than twice per week at home. The first home administration must be at least 24 hours post Visit 1. The subject will be required to complete the International Index of Erectile Function (IIEF) questionnaire post-dose at home dosing, along with the Subject Diary Card.

The subject will return on Visit 2, 3 and Visit 4 at 4-weekly intervals after Visit 1 (+/-3 days). The Subject Diary cards and IIEF questionnaires will be collected and reviewed for compliance. At Visit 2, 3 and 4 the subject will undergo a physical examination, ECG and vital signs. The subject will complete sexual function questionnaires. The subject will receive Invicorp 2.5mcg/2ml via Intra-Cavernosal Injection. A Rigiscan will be performed approximately 15 minutes post dose. Adverse Events and Concomitant Medications will be recorded.

After the completion of the study procedures at each visit, the subject will be dispensed study drug for up to twice weekly at-home dosing along with Subject Diary Cards diaries and IIEF questionnaires for subsequent data collection. Subjects will be instructed to use Invicorp before anticipated sexual intercourse. Subjects will also be instructed that Invicorp injections must not be used more than once per day and no more than twice per week at home. The first home post visit administration must be at least 24 hours post each clinic visit. The subject will be required to complete the International Index of Erectile Function (IIEF) questionnaire post at home dosing, along with the Subject Diary Card.

A follow up visit will be scheduled 14 days post Visit 4(+/-7 days). Blood samples for Haematology and Chemistry levels will be collected. The Subject Diary cards and IIEF questionnaires will be collected and reviewed for compliance. A physical examination, vital signs and an ECG will be performed. Adverse Events and Concomitant Medications will be recorded.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)

VIP (Vasoactive Intestinal Peptide), aviptadil (25mcg), phentolamine (2mg) [Invicorp]

Primary outcome(s)
Sexual function questionnaire (International Index of Erectile Function [IIEF-15]) collected pre-dose at the Screening Visit, Visit 1, 2, 3 and 4

Key secondary outcome(s)
1. Penile rigidity and tumescence measured using the Rigiscan Plus Monitor at Visit 1 approximately 15 minutes post Invicorp administration. They will also be performed at Visits 2, 3 and 4, approximately 15 minutes post study drug administration. Rigiscans should be performed as per the Rigiscan User Manual.
2. Sexual function questionnaires pre- and post-surgery
2.1. Erection hardness score (EHS);
2.2. SEAR (self-esteem and relationship) questionnaire;
2.3. SEP (sexual encounter profile) question 2 and 3 only.
3. Safety and tolerability of Invicorp measured using adverse events and Subject Diary cards throughout the study

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Willing and able to provide written informed consent.
2. Adult (18 years or older), male subjects with diagnosis of prostate cancer and scheduled radical prostatectomy either nerve sparing and non-nerve sparing.
3. In generally good health in the opinion of the Investigator.
4. Willing and able to comply with all study procedures in the opinion of the Investigator.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Male

Total final enrolment
24

Key exclusion criteria

1. History of a significant medical condition that would preclude further study participation, in the opinion of the Investigator.
2. Symptoms suggestive of COVID-19 infection and positive PCR test.
3. Undergone radiotherapy post radical prostatectomy.
4. Received chemotherapy post radical prostatectomy.
5. Experiencing significant incontinence post operatively.
6. Use of PDEV inhibitors within 1 month prior to the screening visit.
7. History of allergy to aviptadil or phentolamine mesilate or any of the other ingredients of the study medicine Invicorp.
8. Current diagnosis or history of leukaemia (cancer of the blood), multiple myeloma (bone cancer) or sickle cell anaemia or trait (a blood disease).
9. Currently taking anticoagulant agents such as warfarin or heparin, (except low molecular weight heparin given subcutaneously for venous thromboembolism prophylaxis), including oral blood thinning medicines such as dabigatran, rivaroxaban, apixaban within 1 month prior to the screening visit.
10. Anatomical deformation of the penis, such as angulation, history of Peyronie's disease or abnormal fibrous tissue in the erectile tissue of the penis (cavernosal fibrosis).
11. Subject has penile implant.
12. Men for whom sexual activity is not advisable or is contraindicated due to organic disease.
13. Positive for hepatitis B, hepatitis C, or HIV infection.
14. Safety testing abnormalities at the Screening Visit, that are indicative of a medical condition and that would preclude further participation, in the opinion of the Investigator.
15. Subject unwilling to perform study drug home administration.
16. History of alcohol or drug abuse within 1 year prior to the Screening Visit.
17. Use of an investigational (non-registered) drug within 30 days before the first Screening Visit

Date of first enrolment
22/08/2022

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nephro-Urology Clinical Trials
Fitzrovia Hospital
13-14 Fitzroy Square
London
United Kingdom
W1T 6AH

Sponsor information

Organisation
RestoriT Ltd

Funder(s)

Funder type
Industry

Funder Name
RestoriT Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from brian.leaker@qasmc.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No