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The Comfort study

Submission date	Recruitment status	[_] Prospectively registered
03/02/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/02/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/06/2020	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Radical prostatectomy (RP) is the most common treatment for prostate cancer in North America. It is an operation where the prostate gland is removed in order to remove the cancer. About 1% of all men undergoing RP develop complete urinary incontinence. Another 6 to 30% of patients are left with mild to moderate urinary incontinence requiring lifestyle changes, protective garments, external devices or corrective surgery. Unfortunately, many devices require surgical implantation and have a significant failure rate (30-50%). There are non-surgical solutions available but poor outcomes and associated pain have resulted in low patient acceptance. A nonsurgical, comfortable urinary occlusion device is attractive to patients who do not wish to undergo surgical correction or uncomfortable clamping. A simple urethral plug, developed by a prostate cancer survivor and worn for 9+ years without incident, is the basis for this study. This is a first-in-human study to assess the safety, effectiveness, comfort and usability of the prototype Comfort Plug™ for controlling urinary incontinence in men.

Who can participate?
Men aged 18 and over with urinary incontinence

What does the study involve?
Participants are fitted with the Comfort Plug™ on Day 0 and receive training from the investigator on how to self-insert, clean and remove the plug. Participants self-insert and remove and clean the Comfort Plug™ each time urination is necessary. The plug is not used overnight. Participants use the device from Day 0 to Day 30. Days 0 to 14 are considered a familiarization period where the participants get accustomed to using the device. Days 14 to 30 are considered the assessment period. Participants complete a pad use diary over 24 hours before the clinic visits on Day 0, Day 14 and Day 30. Participants also complete a daily diary on days 7 to 30 to document the times when the Comfort Plug™ is inserted and removed, times of voiding and issues related to leakage if any. Leakage of urine is also assessed by measuring incontinence pad weight throughout the duration of the study. Participants wear their pads for 24 hours before each clinic visit (Day 0, 14 and 30) and return the pads at the visit. Participants are evaluated for safety and ability to use the device at Days 1, 3 and 7 with a follow-up conducted by telephone. On Days 14 and 30 participants have a follow-up visit at the clinic. A final safety telephone follow-up is conducted at Day 56.

What are the possible benefits and risks of participating?
The device may be effective for treating urinary incontinence and may be free of side effects. The most common side effects that may occur include: haemorrhage (bleeding), pressure ulcer (tissue injury), urethral puncture (hole in urethra), infection, septicaemia (blood infection), coloured discharge, fever, burning, urethral pain, pain in your side, lower abdominal pain, severe irritation, confusion or disorientation. An allergic reaction is possible. This can be mild, with a rash or itching; to life-threatening, with severe rash, trouble breathing or swallowing. The risks of stretching the opening to your penis include pain, bleeding, infection, tearing or scarring. Blood collection also has minimal risks which include dizziness, pain or bruising at the site where the needle was inserted. The total amount of blood to be drawn for study purposes is about 20 mL (about 4 teaspoons) over 13 weeks.

Where is the study run from?
Life360 Innovations Inc. (Canada)

When is the study starting and how long is it expected to run for?
January 2014 to December 2018

Who is funding the study?
Life360 Innovations Inc. (Canada)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
CMX Study Number: CMX-UR-2013-004 No. 1 to No. 4

Study information

Scientific Title
Validation study: a prospective, non-randomized, single-arm trial to assess the efficacy of the Comfort Plug in preventing urinary incontinence in male subjects with sphincteric incompetence

Study objectives
The main objective of this study is to establish the safety and effectiveness of the Comfort Plug™, where safety is characterized by the absence of complications and effectiveness is characterized by the ability to stop involuntary urine flow.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board Services (IRB Services), 19/11/2013, ref: CMX-UR-2013-004

Study design
Multicenter single-arm prospective non-randomized single-arm trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Sphincteric incompetence in adult males

Interventions
Only incontinent men with sphincteric incompetence, including those who have undergone radical prostatectomy, will be screened. All subjects who meet entry criteria will receive Comfort Plug™ instructions and treatment. Any patient who inserts a Comfort Plug™ will be considered enrolled into the trial. As this is a proof of concept study with a new device, a review will be performed after the study completion of every 5 enrolled subjects. Design modifications to the Comfort Plug™ may be made during the study if further improvements are indicated (e.g. safety) prior to proceeding to the next cohort.

The Comfort Plug™ will be placed into the urethra. The subject will receive training from the investigator on Day 0 on the proper techniques for insertion and removal. Subjects will self-insert and will remove and clean the Comfort Plug™ each time urination is necessary. The plug will not be used overnight. Subjects will be required to use the device from Day 0 to Day 30. Days 0 to 14 will be considered a familiarization period where the subjects can get accustomed to the use of the device. Days 0 to 6 will involve a week of the subjects becoming accustomed to the use of the Comfort Plug™ and practicing inserting and removing it. Days 7 to 13 will involve a week of the subjects wearing the device. Days 14 to 30 will be considered the assessment period with the majority of subject data being collected during this time. Subjects will complete a Pad Use diary over 24 hours prior to the clinic visits on Day 0, Day 14 and Day 30. Subjects will also complete a daily diary on days 7 to 30 to document the times when the Comfort Plug™ is inserted and removed, times of voiding and issues related to leakage if any. Subjects will be evaluated for safety and ability to use the device at Days 1, 3 and 7 (±1 day) via a follow-up conducted by telephone. On Days 14 and 30 (± 2 days) subjects will have a follow-up visit at the clinic. A final safety telephone follow-up will be conducted at Day 56 (± 4 days).

Up to 30 subjects will be enrolled; five subjects per cohort. All data from each cohort of 5 subjects will be reviewed and a decision will be made to either continue enrollment with the current prototype iteration or make changes prior to continuing. If a newly designed prototype is introduced, data for the first 5 subjects enrolled in the next cohort will be reviewed prior to continuing enrollment. Safety will be assessed throughout the study prior to proceeding with further cohorts.

The Sponsor may choose to stop the study early if study data indicates that the current iteration meets the Sponsor's performance criteria and moving into a larger controlled trial is warranted. However, enrolled subjects will be allowed to complete the study.

Study Variables
Device Performance
1. Effectiveness as measured by incontinence pad weight and ICIQ-SF score
2. Comfort assessed by the Follow-up Questionnaire
3. Usability assessed by the Follow-up Questionnaire
4. Quality of Life assessed by the Incontinence Quality of Life (I-QOL) Instrument

Safety Review
1. Adverse events
2. Assessment of AEs leading to the discontinuation of the study device
3. Clinical and laboratory data including physical examinations and vital signs
4. Use of concomitant medications

Study Procedures and Assessments
Device Performance
Subjects will be required to remove and then re-insert the Comfort Plug™ each time they urinate during waking hours. Effectiveness, comfort and usability of the Comfort Plug™ will be determined by subject responses to the Follow-up Questionnaire.

Effectiveness
Leakage of Urine will be assessed by measuring incontinence pad weight throughout the duration of the study. Subjects will wear their pads 24 hours prior to each clinic visit (Day 0, 14 and 30) and return the pads at the respective clinic visit. Clinic staff will pre-weigh the pads before providing them to the subjects and will weigh them once returned to the clinic. Leakage experienced by the subjects will also be rated using the ICIQ-SF. Pads used during daytime and during the night should be weighed separately.

Comfort
Subjects will provide feedback on the comfort of using the Comfort Plug™ on the Follow-up Questionnaire.

Usability
Subjects will provide feedback on the level of ease inserting and removing the Comfort Plug™ on the Follow-up Questionnaire. Overall, usability will be assessed by the number of subjects that would continue if they had the opportunity when the study completed.

Safety
Adverse Events will be collected at each telephone contact and visit to the clinical facility. A

physical examination, including vital sign measurements, will be performed at Visit Day 0 and Visit Day 30. Clinical safety laboratory assessments will be measured at the screening visit and Visit Day 30.

Sample Size and Statistical Analyses
No assessment for statistical significance has been performed or is planned. The sample size of 30 is based on clinical judgment and is believed to be sufficient to meet the objectives of this study. Relevant study variables will be summarized descriptively.

Intervention Type
Device

Primary outcome(s)
1. Effectiveness as measured with the ICIQ-SF score at baseline (Visit Day 0) and Visit Days 7 and 30 (cohort 1) or Visit Days 14 and 30 (subsequent cohorts)
2. Effectiveness as measured by incontinence pad weight at baseline (Visit Day 0) and at Visit Days 7 and 30 (cohort 1) or Visit Days 14 and 30 (subsequent cohorts)
3. Adverse events collected at each telephone contact and visit to the clinical facility
4. Clinical and laboratory data including physical examinations and vital signs at at Visit Day 0 and Visit Day 30

Key secondary outcome(s))
1. Quality of life assessed by the Incontinence Quality of Life (I-QOL) Instrument at baseline and Visit Days 7 and 30 (cohort 1) or Visit Days 14 and 30 (subsequent cohorts) for:
1.1. Avoidance and Limiting Behaviour
1.2. Psychosocial Impacts
1.3. Social Embarrassment
2. Number of subjects who discontinue use of the Comfort Plug™ due to lack of comfort
3. Number of subjects that would continue using the Comfort Plug™ if given the opportunity, assessed using the Follow-up Questionnaire
4. Level of ease of use inserting the Comfort Plug™, assessed using the Follow-up Questionnaire
5. Level of ease of use removing the Comfort Plug™, assessed using the Follow-up Questionnaire
6. Level of satisfaction with the Comfort Plug™, assessed using the Follow-up Questionnaire
7. Number of subjects with newly observed urinary function improvements, including (but not limited to): being able to urinate independently for the first time since prostate surgery, return of urge to void and sensation of full bladder, better urinary stream, reduced time urinating, assessed using the Follow-up Questionnaire

The subjects complete the activity of the trial at day 30 and there is a close out period of the study that takes place over the next 30 days (Follow-up Questionnaire, blood work, health examination by the doc., return of materials, etc.). At day 56 +/- 3 days a study nurse contacts the subject to confirm that everything is completed and the subject is still in good health.

Completion date
31/05/2018

Eligibility

Key inclusion criteria
1. Male 18 years of age or older
2. Evidence of sphincteric incompetence as assessed by the Investigator

3. Cystoscopic evaluation of the lower urinary tract within 24 months of screening
4. ECOG 0 or 1 performance status
5. Evidence of moderate to severe urinary incontinence, as assessed by the Investigator, requiring protective garments or pads
6. Post surgical PSA < 5 ng/ml

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
1. Inability to insert the Comfort Plug™ into his own urethra and remove it
2. Less than 6 months post radical prostatectomy for localized prostate cancer
3. History of significant incontinence prior to radical prostatectomy
4. Evidence of neurogenic bladder dysfunction resulting in uncontrolled contractions
5. Untreated urethral stricture disease
6. History of meatal stenosis or phimosis
7. Use of anticoagulant or antiplatelet medications excluding low-dose ASA
8. Any cardiac condition that requires the use of pre-procedure antibiotic prophylaxis such as a mechanic valve
9. Body Mass Index (BMI) greater than 32 kg/m2
10. Known immune deficiency either due to disease or medications
11. Uncontrolled diabetes (in the opinion of the Investigator)

Date of first enrolment
20/01/2014

Date of final enrolment
31/01/2018

Locations

Countries of recruitment
Canada

Study participating centre
Dr Richard Casey
The Fe/Male Health Centres

Suite 407, 1235 Trafalgar Road North
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Sponsor information

Organisation

Life360 Innovations Inc.

Funder(s)

Funder type
Industry

Funder Name
Life360 Innovations Inc.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as general sharing was not contemplated when the informed consent was put together in late 2013. The trialists are able to share de-identified raw data for regulatory purposes only.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	conference abstract	02/06/2020	12/06/2020	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes