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Analysis of the TrueClr external catheter's effectiveness in emptying the bladder

Submission date
20/06/2023

Recruitment status
No longer recruiting

Registration date
28/06/2023

Overall study status
Completed

Last Edited
21/06/2023

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
The aim of this study is to determine the effectiveness of the TrueClr External Catheter at emptying the bladder, as well as patients' and medical professionals' satisfaction with the safety and comfort of the TrueClr.

Who can participate?
Men aged 18 years and over who may benefit from the use of a urinary catheter

What does the study involve?
The TrueClr catheter is used to empty the participant's bladder. The volume of urine collected is measured and patients' and medical professionals' satisfaction is assessed.

What are the possible benefits and risks of participating?
The benefit may include increased comfort and safety of emptying the bladder with the TrueClr over traditional catheter systems, whilst the risk entails the TrueClr's failure to empty the bladder, thus requiring the subsequent use of a traditional catheter system.

Where is the study run from?
Urologcentrum Liljeholmen (Sweden)

When is the study starting and how long is it expected to run for?
April 2023 to October 2023

Who is funding the study?
Mareld Medical AB (Sweden)

Who is the main contact?
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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CIV-23-04-042855

Study information

Scientific Title
TrueClr Sweden pilot study 2023-01

Acronym
TrueClr Swe 2023-01

Study objectives
Primary:
Patients will prefer TrueClr's active external design as a safer and more comfortable alternative to internal catheter systems.

Secondary:
Medical professionals will prefer TrueClr's active external design as a safer and more comfortable alternative to internal catheter systems.

Ethics approval required
Ethics approval not required

Ethics approval(s)
This clinical investigation does not require an ethical review since:
1. The clinical investigation is conducted to further assess, within the scope of its intended purpose, a device which already bears the CE mark and the investigation does not involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device, or if additional procedures aren't invasive nor burdensome, a notification to the Swedish MPA needs to be submitted at least 30 days before the investigation is initiated, according to the provisions HSLF-FS 2021:32.
2. The entity responsible for the research (i.e. the principal investigator) has determined that the investigation is not subject to an ethical review.
3. Therefore, the clinical investigation will commence when at least 30 days have passed since the notification was confirmed by the Swedish Medical Products Agency.

Study design
Single-center non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other therapist office

Study type(s)
Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Urology (urine retention)

Interventions
The TrueClr External Catheter will be applied to the penises of participating subjects, after which the aspirator will be activated to apply suction to the penis. The TrueClr will remain applied for 10-30 minutes, or until the bladder of the subject has been emptied.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
UR24 technology TrueClr M/M+

Primary outcome measure
The TrueClr external catheters' efficacy in emptying the bladder will be measured by recording the volume of urine collected. Extracted urine volume is measured in mL after the intervention.

Secondary outcome measures
1. Patient satisfaction levels with safety and comfort recorded on a Visual Analogue Scale, with levels ranging from 1-10 (1 being extremely unsatisfied and 10 being extremely satisfied), after the intervention
2. Medical professional satisfaction levels with safety and comfort recorded on a Visual Analogue Scale, with levels ranging from 1-10 (1 being extremely unsatisfied and 10 being extremely satisfied), after the intervention

Overall study start date
27/04/2023

Completion date
12/10/2023

Eligibility

Key inclusion criteria
Male patients aged 18 years and over benefitting from the use of a urinary catheter

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
25

Key exclusion criteria
Urethral stricture or other conditions negating the efficacy of an external urinary catheter

Date of first enrolment
20/06/2023

Date of final enrolment
20/09/2023

Locations

Countries of recruitment
Sweden

Study participating centre
Urologcentrum Liljeholmen
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Sponsor information

Organisation
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Mareld Medical AB

Results and Publications

Publication and dissemination plan
The study results are to be used for marketing and commercial interest, mainly in the Nordic countries as well as in the United States.

Intention to publish date
31/10/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to patient confidentiality.

IPD sharing plan summary
Not expected to be made available