

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

Submission date 20/06/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/06/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 21/06/2023	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Efficacy

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

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

UR24 technology TrueClr M/M+

Primary outcome(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Male

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

Liljeholmstorget 7

Stockholm

Sweden

117 63

Sponsor information

Organisation

Mareld Medical AB

Funder(s)

Funder type

Industry

Funder Name

Mareld Medical AB

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 due to patient confidentiality.

IPD sharing plan summary

Not expected to be made available