Clinical investigation to evaluate the performance and safety of Ambu® aScope* 4 Cysto and aView* Urologia for flexible cystoscopy.

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Evaluate the performance of Ambu® aScope* 4 Cysto and aView* Urologia for direct visualization and treatment of the urethra and bladder.Evaluate the patient tolerance to the procedure and the procedural time of Ambu® aScope* 4 Cysto and aView*...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Urinary tract signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON54961

Source
ToetsingOnline

Brief title
Performance and safety aScope 4 Cysto

Condition

- Urinary tract signs and symptoms

Synonym
abnormalities in urethra and bladder

Research involving
Human

Sponsors and support

Primary sponsor: Ambu AS

Source(s) of monetary or material Support: AMBU AS

Intervention

Keyword: Cystoscopy, Performance, Safety, Urinary bladder

Outcome measures

Primary outcome

The aim of this study is to evaluate the performance and safety of Ambu®

aScope* 4 Cysto and aView* Urologia for flexible cystoscopy.

Primary endpoint: - Rate of completion of procedure with Ambu® aScope* 4 Cysto

and aView* Urologia (Yes/No, Yes applies to 80% of procedures)

Secondary outcome

- Rate of overall performance during the procedure

- Rate of pain level experienced by the subject when inserting the flexible

cystoscope (measured on a visual analog scale

- Overall procedure time from insertion of flexible cystoscope to removal

The intended performances that will be investigated during this clinical

investigation are:

* Manoeuvrability

o Insertion of the endoscope in the lower urinary tract

o Navigation in the bladder

o Use of endoscopic accessories in the working channel

* Use of the working channel (eg. Irrigation and tools)

* Visual examination of the urothelium

* Visual confirmation of anatomical structures

* Visual confirmation of abnormalities in urethra and bladder

Study description

Background summary

A prospective, multicenter, single- arm open-label clinical study on the performance and safety of Ambu® aScope* 4 Cysto and aView* Urologia, a single-use, flexible cystoscope for flexible cystoscopy. The study will be executed in adult subjects (* 18 years) undergoing flexible cystoscopy for diagnostic or therapeutic purposes. The subjects should be above 18 years of age or older, presenting for cystoscopy and ambulatory with a need to undergo cystoscopy for diagnostic or therapeutic purposes.

The study is executed for post-CE mark purposes. The monitor used is also investigated to understand to assess the visualisation performance. The monitor is CE approved.

Study objective

Evaluate the performance of Ambu® aScope* 4 Cysto and aView* Urologia for direct visualization and treatment of the urethra and bladder.
Evaluate the patient tolerance to the procedure and the procedural time of Ambu® aScope* 4 Cysto and aView* Urologia for direct visualization and treatment of the urethra and bladder

Study design

A prospective, multicenter, single- arm open-label clinical study on the performance and safety of Ambu® aScope* 4 Cysto and aView* Urologia, a single-use, flexible cystoscope for flexible cystoscopy

Intervention

The subjects will undergo a cystoscopy procedure.

Study burden and risks

There are no direct risks foreseen for participation in the study, as the cystoscope is only used for viewing and the duration of the flexible cystoscopy will normally take 10-15 minutes. The subject will be given local anaesthetics which is standard clinical practice for this procedure. The subject might experience some pain when inserting the cystoscope. For the next 24 hours the

subject may have a mild burning feeling when urinating and increased voiding frequency. Mild bleeding can be present in the urine if biopsy or botox injections are performed and the subjects takes blood thinning medication. This are all symptoms which can be seen after cystoscopy using standard cystoscopes.

Contacts

Public
Ambu AS

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DK
Scientific
Ambu AS

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

i. Adults (males and females), *18 years of age or older, presenting for cystoscopy
ii. Ambulatory with a need to undergo cystoscopy for diagnostic or therapeutic purposes
iii. Willing to participate in a clinical trial

Exclusion criteria

i. History of high-grade bladder cancer or carcinoma-in-situ of the bladder, undergoing cystoscopy for follow-up/surveillance purposes
ii. History of prior bladder/urethral reconstructive surgery
iii. Presence of symptomatic urinary tract infection (UTI)
iv. Known unpassable urethral stricture
v. Unable to read and/or understand the study requirements
vi. Unable or unwilling to provide consent to participation in the study
vii. Pregnant or lactating women

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-07-2020
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Cystoscope (for CE submission) and monitor (CE marked)
Registration:	No

Ethics review

Approved WMO

Date:	12-03-2020
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-06-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-09-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-12-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-03-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL72049.078.19