Initial Case Series with Exalt Single-Use Duodenoscope * Expanded User Experience

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The objective of this study is to confirm procedural performance of the Exalt single-use duodenoscope in Endoscopic Retrograde Cholangiopancreatography (ERCP) or other duodenoscope-based procedures.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON49147

Source
ToetsingOnline

Brief title
Exalt DScope 01B

Condition

- Gastrointestinal conditions NEC
- Gastrointestinal therapeutic procedures

Synonym
a long flexible tube with a camera on the tip, duodenoscope

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific
Source(s) of monetary or material Support: Boston Scientific Corporation

Intervention

Keyword: duodenoscopes, endoscopic retrograde cholangiopancreatography

Outcome measures

Primary outcome

The primary endpoint of the trial is the ability to complete the ERCP or other duodenoscope-based procedures for the intended indication(s).

Secondary outcome

The following will be recorded as secondary endpoints during index procedure through follow-up:

1. Document endoscopist rating of the Exalt single-use duodenoscope compared to marketed reusable duodenoscopes as it pertains to various design and performance related attributes.

2. Incidence of crossover from Exalt single-use duodenoscope to reusable duodenoscope.

3. Evaluation of serious adverse events (SAEs) related to the device and/or the procedure through 30 days after the ERCP or other duodenoscope-based procedure.

Study description

Background summary

Flexible endoscopes are used globally for the diagnosis and treatment of diseases of the GI tract. These delicate instruments are used in Endoscopic Retrograde Cholangiopancreatography (ERCP) procedures, which are performed with side viewing endoscopes (duodenoscopes) that to date are all reusable devices. Given their reusability, these instruments must be reprocessed through high level disinfection (HLD) in order to prevent the spread of nosocomial infections, although different levels of disinfection may be produced depending on disinfection method, device modification, and staff adherence to

disinfection protocols.

In recent years there have been an increased number of nosocomial infection outbreaks traced to contaminated duodenoscopes used during ERCP procedures in many states throughout the US and Europe. Organisms involved in these recent outbreaks include Carbapenem-resistant Enterobacteriaceae (CRE), including Escherichia coli, and Klebsiella pneumoniae. Unfortunately, some of the cases linked to these outbreaks have proven to be fatal. Typically, infections discovered post-ERCP procedures vary between 2%-4%, but it is unclear whether these infections are caused by contaminated duodenoscopes or the procedure.

The gastrointestinal tract is a highly contaminated environment, and the intricate tip design and long, narrow working channels of modern duodenoscopes render them extremely difficult, if not impossible, to adequately clean. Even strict adherence to all HLD procedures results in a non-zero, although minimal, level of potentially infectious microbes. Months after initial reports of duodenoscope linked infections surfaced in the US, the FDA stated that they were warning manufacturers, monitoring, and providing closer surveillance in an effort to prevent further infections associated with contaminated duodenoscopes.

In summary, conventional reusable duodenoscopes have been identified as the source of multiple cases of fatal and nonfatal nosocomial infections throughout the US and Europe, despite adherence to duodenoscope sterilization and reprocessing guidelines. The infectious organisms were later identified as belonging to a family of bacteria that has a high level of resistance to conventional antibiotics, known as CRE. To date, there are no single-use disposable duodenoscopes available in the open market, which do not need to be sterilized or reprocessed because they are only used for a single patient in one case before they are disposed of. The availability of such a device may save patient lives by removing a potential source of infection and save the healthcare system money used to treat the infections and to reprocess the devices.

Study objective

The objective of this study is to confirm procedural performance of the Exalt single-use duodenoscope in Endoscopic Retrograde Cholangiopancreatography (ERCP) or other duodenoscope-based procedures.

Study design

This is a prospective, multi-center case series of per standard of care ERCP procedures of up to 200 cases. The endoscopist will use the Exalt single-use duodenoscope in place of the reusable duodenoscope normally used in the endoscopy unit at their own discretion.

Intervention

Subjects will have their clinically indicated ERCP or other duodenoscope-based procedure performed using the Exalt single-use duodenoscope.

Study burden and risks

The following potential anticipated adverse events (AE) and anticipated adverse device effects (ADE) which may be associated with the use of a generic reusable duodenoscope and type of procedure as well as related to the use of the Exalt Single-Use Duodenoscope have been identified for this study:
* Perforation
* Bleeding
* Infection
* Tissue damage
* Pain
* Air Embolism
* Burn
* Allergic Reaction
* Electric Shock

Additional risks may exist which are unknown at this time. Risks can be minimized through compliance with this protocol, performing procedures in the appropriate hospital environment, adherence to patient selection criteria, close monitoring of the patient*s physiologic status during research procedures and/or follow-ups and by promptly supplying the Sponsor with all pertinent information required by this protocol. Patient risk is further minimized by placing no restriction on an investigator*s decision to stop using the Exalt duodenoscope and switch to their standard duodenoscope.
Patients may not receive any benefit from participating in this study. However, medical science and future patients may benefit from this study. Based on collected reports in literature to-date, the risk-to-benefit ratio is within reason for foreseeable risks. However, literature reports do not always capture all side effects. Observation and follow-up of patients is required as outlined in the protocol.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. 18 years or older
2. Willing and able to comply with the study procedures and provide written informed consent to participate in the study
3. Scheduled for a clinically indicated ERCP

Exclusion criteria

1. Potentially vulnerable subjects, including, but not limited to pregnant women
2. Subjects for whom endoscopic techniques are contraindicated
3. Subjects who are currently enrolled in another investigational study that would directly interfere with the current study, without prior written approval from the sponsor
4. Investigator discretion

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-02-2021
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Exalt Model D Single-Use Duodenoscope
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	19-01-2021
Application type:	First submission
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
ClinicalTrials.gov	NCT04223830
CCMO	NL75192.078.20