Validation of the Japanese Esophageal Society classification for prediction of invasion depth of superficial squamous cell carcinoma in a Western population

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26261

Source
Nationaal Trial Register

Brief title
VISTA

Health condition

All patients with a suspicious or known (pre)malignant esophageal squamous cell lesion

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The overall accuracy of the JES-classification for predicting the invasion depth of ESCC

Secondary outcome

- Presence and size of avascular areas in the esophageal squamous cell lesions.
- Paris-classification of the esophageal squamous cell lesions.
- Presence of intervascular background coloration.
- Positive/negative pink color sign with Lugol's iodine staining.
- The predicted invasion depth of the esophageal squamous cell lesions considering the above mentioned parameters.
- Inter- and intraobserver agreement between Western expert endoscopists and non-expert endoscopists, and Japanese endoscopists.

Study description

Background summary

The objective of this study is to validate the JES-classification for prediction of invasion depth of superficial squamous cell carcinoma by Western endoscopists in a Western population. This is a multicenter observational study.

Study objective

The JES-classification can be used for predicting invasion depth in esophageal squamous cell carcinoma (ESCC) in Western patients

Study design

After collection of all available endoscopic photos and videos from previously treated patients, the photos and videos will be analyzed by multiple expert endoscopists and non-expert endoscopists.

Intervention

Endoscopic photos and videos of white light endoscopy (WLE), magnification endoscopy, NBI and lugol's iodine staining from previously treated patients with ESCC will be collected. The photos and videos will be analyzed prospectively by multiple assessors. The ESCC lesions will be scored on their invasion depth by using the microvessel pattern according to the JES-classification.

Contacts

Public

St. Antonius Ziekenhuis
Ilse Beaufort

088-3206043
Scientific
St. Antonius Ziekenhuis
Ilse Beaufort

088-3206043

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Western patients with a suspicious or known (pre)malignant esophageal squamous cell lesion
- Photos and videos available using WLE, magnification endoscopy, NBI, and (when available) lugol's iodine staining.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from any analysis with regard to the prediction of invasion depth:
- No data on histological invasion depth available.
- Patients who underwent esophagectomy with neoadjuvant (chemo)radiation therapy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status:	Recruiting
Start date (anticipated):	01-08-2020
Enrollment:	94
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion
Date:	06-09-2020
Application type:	First submission

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
NTR-new	NL8897
Other	MEC-U : W19.234

Study results

Summary results
N/A