

Effectiveness of full-thickness resection of subepithelial tumors using the Pro-select Padlock clip

No registrations found.

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

Summary

ID

NL-OMON26700

Source

Nationaal Trial Register

Sponsors and support

Primary sponsor: UMC Utrecht

Source(s) of monetary or material Support: UMC Utrecht

Intervention

Outcome measures

Primary outcome

Proportion of cases where radical resection of the SET is achieved

Secondary outcome

- Proportion of cases where full thickness resection is achieved
- Number of severe adverse events
- Technical difficulties with Padlock clip

Study description

Study objective

We hypothesize that the commercially available CE-marked over the scope Pro-select Padlock clip is able to clip a gastric/duodenal SET, where after full thickness resection of the SET can be achieved using a normal

Study design

Baseline:

patient/SET characteristics

Endoscopy; procedure data

1 week telephone call: (severe) adverse events

1 month telephone call: (severe) adverse events

3 months endoscopy: procedure data

Intervention

Full thickness resection with a padlock clip

Contacts

Public

P.O. box 85500
University Medical Center Utrecht
Department of Gastroenterology & Hepatology
Room F02.618
W.F.W. Kappelle
Utrecht 3508 GA
The Netherlands
+31 (0)88 5750724

Scientific

P.O. box 85500
University Medical Center Utrecht
Department of Gastroenterology & Hepatology

Room F02.618
W.F.W. Kappelle
Utrecht 3508 GA
The Netherlands
+31 (0)88 5750724

Eligibility criteria

Inclusion criteria

All patients undergoing full thickness resection of a subepithelial tumor in stomach or duodenum with a Padlock clip on the endoscopy department of the University medical center of Utrecht.

Exclusion criteria

None

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-03-2015
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date: 17-02-2015

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	NL4921
NTR-old	NTR5023
Other	Ethics committee Utrecht : 15-084

Study results