Voorkoming van nabloedingen na endoscopische mucosale resectie (EMR) van de slokdarm, twaalfvingerige darm en de dikke darm.

No registrations found.

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

Summary

ID

NL-OMON23259

Source
Nationaal Trial Register

Brief title
PATCH study

Health condition

Delayed bleeding, nabloeding.
EMR, endoscopische mucosale resectie.
Esofagus, esophagus, oesofagus, oesophagus.
Duodenum.
Colon.

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: Sponser initiated

Intervention

Outcome measures

Primary outcome

Feasibility and safety of Purastat application, including the volume used per cm2 of resection surface, EMR procedure time, duration of gell application and side effects of Purastat application.

Secondary outcome

- DB within 30 days post-procedure
- Severity of DB
- Hospital presentations after EMR
- Type and number of interventions, e.g. colonoscopy, surgery, angiography with or without coiling
- Blood transfusions
- Perforation rate
- Length of hospital and intensive care unit (ICU) stay

Study description

Background summary

Rationale: Purastat is a matrix gel with aminoacid components aiding to cell recovery after tissue damage. Previous studies have shown that Purastat can be applied safely and effectively in oozing bleedings after ESD and has a stimulating effect on wound healing after 4 and 8 weeks. Based on these findings, it is hypothesized that Purastat has a beneficial effect on delayed bleeding rates after endomucosal resection (EMR) procedures.

Objective: To determine the feasibility and safety of Purastat for the prevention of delayed bleedings after EMR in the esophagus, duodenum and colon.

Study design: Prospective cohort study.

Study population: Patients >18 years old undergoing EMR for polyps or premalignant tissue such as Barrett’s esophagus, duodenum and/or colon.

Main study parameters/endpoints: Primary endpoints are the feasibility and safety of Purastat application. Secondary endpoints included the incidence of delayed bleedings within 30 days post procedure, defined as clinical significant blood loss for upper and lower GI.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: As the application during the endoscopy is not invasive in itself, there is no significant burden for the patient. The number of hospital visits for the patients will not be

influenced, and will all be part of standard of care.

Study objective

The application of Purastat on the woundsurface will be feasible and safe.

Study design

- Day 0: application of Purastat after EMR-procedure
- Day 30: check if a DB did occur, and if so: collect additional information.

Intervention

Patients who undergo EMR of the esophagus, duodenum or colon will be treated with prophylactic Purastat application as standard of care.

Contacts

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Eligibility criteria

Inclusion criteria

- Age >18 years old

- EMR of the:

o Esophagus with lesions showing low- or high grade dysplasia within a Barrett segment or intramucosal cancer of 1-3 cm

o Duodenum with lesions suspected as high-grade dysplasia or intramucosal cancer and measuring 1-3 cm in size

o Colon with flat or sessile adenomas measuring 20 mm or larger.

- Written informed consent

Exclusion criteria

- Other prophylactic treatment, such as prophylactic clipping.

- Major intraprocedural bleedings during EMR, for which intervention other than Purastat is indicated (e.g. clip deployment). NB. Prophylactic coagulation of vessels is allowed as it is preventive for recurrence, but not DB.

- Multiple (>1) lesions treated in the same treatment, or within 30 days before and after the EMR.

- ASA IV en V

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:	Recruitment stopped
Start date (anticipated):	01-06-2018
Enrollment:	50
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-07-2018
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	NL7140
NTR-old	NTR7338
Other	Lokale commissie mensgebonden onderzoek van het Radboudumc : 2018-4392

Study results