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

Gepubliceerd: 03-07-2018 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23259

Bron
NTR

Verkorte titel
PATCH study

Aandoening

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

Ondersteuning

Primaire sponsor: Radboudumc
Overige ondersteuning: Sponser initiated

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2018
Aantal proefpersonen:	50
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	03-07-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7140
NTR-old	NTR7338
Ander register	Lokale commissie mensgebonden onderzoek van het Radboudumc : 2018-4392

Resultaten