'Medroxyprogesterone acetate (MPA) in Familial Adenomatous Polyposis, a proof of principle study’

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The use of progestins in combination with estrogen is associated with a reduced incidence of colorectal carcinoma (CRC)1,2. Also, incidental literature has reported a coincidence of the start of oral contraceptive agents with reduction in polyp...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25407

Bron
NTR

Verkorte titel
MPA in FAP

Aandoening

Familial adenomatous polyposis

Ondersteuning

Primaire sponsor: afdeling maag darm en leverziekten LUMC
Overige ondersteuning: afdeling maag darm en leverziekten LUMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in polyp burden

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
The use of progestins in combination with estrogen is associated with a reduced incidence of colorectal carcinoma (CRC)1,2. Also, incidental literature has reported a coincidence of the start of oral contraceptive agents with reduction in polyp number in a girl with Familial Adenomatous Polyposis (FAP)3. In this study we test the hypothesis that progestins may reduce reduction polyp burden in patients with Familial Adenomatous Polyposis (FAP), a familial polyposis syndrome.

Objective:

To assess in a cohort of patients with established FAP:

1 The efficacy of MPA in terms of reduction of number of colonic polyps, by means of Endoscopic Appearance of Polyposis (EAP) index.

2 The effect on histological parameters and biological response of MPA medication.

Study design:
This is an open label, proof-of-principle study in which 10 female patients will receive MPA (Provera, Pfizer BV) 10 mg/day orally for 4 months. At baseline and four months patients will undergo colonoscopy, with video recording and taking of biopsies. Videos will be assessed for Endoscopic Appearance of Polyposis (EAP) index by an expert panel of gastroenterologists. Biopsies will be assessed for cell proliferation, apoptosis and targets of progesterone signaling.

Study population:
10 female patients with established FAP and intact colon or colonic/rectal remnants, accessible by endoscopy.

Intervention:
All patients receive MPA (Provera, Pfizer BV) in a daily dosage of 10 mg for four months.

Main study parameters/endpoints:

study parameters will consist of:

1 Change in adenoma number or density.

2 Changes in biological and histological parameters.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

• Medication with 10 mg MPA (Provera, Pfizer BV) on a daily basis. Knowledge of nature and prevalence of side effects is largely accounted for by wide experience using this compound as an oral contraceptive agent.

• Two colonoscopies, 8 biopsies will be taken per endoscopy.

Doel van het onderzoek

The use of progestins in combination with estrogen is associated with a reduced incidence of colorectal carcinoma (CRC)1,2. Also, incidental literature has reported a coincidence of the start of oral contraceptive agents with reduction in polyp number in a girl with Familial Adenomatous Polyposis (FAP)3. In this study we test the hypothesis that progestins may reduce reduction polyp burden in patients with Familial Adenomatous Polyposis (FAP), a familial polyposis syndrome.

Onderzoeksopzet

Start and 4 months after start

Onderzoeksproduct en/of interventie

2x colonoscopy with biopsies taken.

Treatment with MPA 10 mg/day for 4 months

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Females > 14 years of age

2. Established FAP, confirmed by prior colonoscopy

3. Patients must be able to adhere to the study visits and protocol requirements

4. Patients must be able to give written informed consent. In case of a minor, parents/legal representative must be able to give a written consent. The consent must be obtained prior to any screening procedures

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Females before menarche

2. Prior progestin use in the past year

3. Change in the use of NSAIDs at least 3 month prior to the study

4. Allergic reaction on MPA during previous use

5. Female patients who are pregnant or breast-feeding.

6. Prior thromboflebitis or thromboembolism.

7. Previous or current serious cardiac or cerebrovascular condition. Like thromboflebitis or thromboembolism, severe hypertension, severe liverfunction disorders. A history of jaundice, herpes gestationis non-explained vaginal bleeding or deterioration of otosclerosis during pregnancy or use of female hormones.

8. Patients with fertility wish for the study period

9. Not available for follow-up assessment

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	04-08-2008
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-08-2008
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	NL1335
NTR-old	NTR1393
Ander register	: 2007-007477-23
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A