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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25407

Source
NTR

Brief title
MPA in FAP

Health condition

Familial adenomatous polyposis

Sponsors and support

Primary sponsor: afdeling maag darm en leverziekten LUMC
Source(s) of monetary or material Support: afdeling maag darm en leverziekten LUMC

Intervention

Outcome measures

Primary outcome

Change in polyp burden

Secondary outcome

Biological response in the target tissue (colon)

Study description

Background summary

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.

Study objective

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.

Study design

Start and 4 months after start

Intervention

2x colonoscopy with biopsies taken.

Treatment with MPA 10 mg/day for 4 months

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	04-08-2008
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-08-2008
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	NL1335
NTR-old	NTR1393
Other	: 2007-007477-23
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A