Effect of pre-operative Simvastatin use on fibrinolytic activity during surgery.

Gepubliceerd: 31-05-2012 Laatst bijgewerkt: 18-08-2022

Statins are able to significantly increase peritoneal fibrinolytic activity.

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

Samenvatting

ID

NL-OMON25154

Bron
Nationaal Trial Register

Aandoening

hysterectomy with or without a unilateral or bilateral salpingooophorectomy per laparotomy for benigne pathology.

Ondersteuning

Primaire sponsor: BWJ Hellebrekers
Haga Teaching Hospital, Department of Gynecology
Leyweg 275
2545 CH The Hague
0702100000
Overige ondersteuning: BWJ Hellebrekers
Haga Teaching Hospital, Department of Gynecology
Leyweg 275
2545 CH The Hague
0702100000

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Change in CRP plasma level from study entry to surgery;
2. Peak plasma level of CRP after surgery;
3. Area under curve of postoperative CRP levels in plasma;
4. tPA concentration in plasma at surgery;
5. tPA activity in plasma at surgery;
6. tPA concentration in peritoneal fluid at surgery;
7. tPA activity in peritoneal fluid at surgery.

Toelichting onderzoek

Achtergrond van het onderzoek

Twenty patients, scheduled for an abdominal hysterectomy with or without a unilateral or bilateral salpingo-oophorectomy for benign pathology are included in this randomized clinical pilot study. Test patients will receive 80 mg Simvastatin per day, three weeks before surgery and one week thereafter, whereas the control patients will receive placebo before and after the surgical procedure. The ability to significantly increase peritoneal fibrinolytic activity will be assessed by comparing the fibrinolytic activity and concentrations of fibrinolytic parameters in peritoneal fluid and plasma in Simvastatin treated patients and controls.

Doel van het onderzoek

Statins are able to significantly increase peritoneal fibrinolytic activity.

Onderzoeksopzet

Blood samples:

I: - 4-8 weeks;

II: -3 weeks;

III: day of surgery;

IV: during surgery;

V: +3 hours;

VI: +6 hours;

VII: +1 day;

VIII: + 2 days;

IX: +3 days;

X: +1 week.

Onderzoeksproduct en/of interventie

Intervention: Simvastatine tablets, 80mg simvastatine a day, 3 weeks before and 1 week after surgery;

Control: Placebo.

Contactpersonen

Publiek

Research nurse gynecology
Haga Teaching Hospital, Department of Gynecology
Leyweg 275
Marianne Hel, van der
Den Haag 2545 CH
The Netherlands
+31 (0)70 2106219

Wetenschappelijk

Research nurse gynecology
Haga Teaching Hospital, Department of Gynecology
Leyweg 275
Marianne Hel, van der
Den Haag 2545 CH
The Netherlands
+31 (0)70 2106219

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. 18 years or older;

2. Scheduled for hysterectomy with or without a unilateral or bilateral salpingooophorectomy per laparotomy for benigne pathology;

3. Good general health with no significant systemic condition at baseline evaluation that would hinder proper outcome assessment.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Non compliance with one or several inclusion criteria;

2. Pregnant women;

3. Haematologic or coagulation disorders;

4. Patient has been diagnosed with a carcinoma or is receiving cancer therapy, including anti-neoplastic drugs and radiation;

5. Patient is already on statin therapy;

6. Patients unavailible for the duration of the study;

7. Presence of ongoing pelvic infection, as for example, ovarian or tubal abscess;

8. Patients participating in another clinical trial
side effects on previous statin treatment;

9. CPK levels >1,5 times ULN at baseline assessment;

10. ALAT levels >1,5 times ULN at baseline assessment;

11. Concomitant liver disease;

12. Renal insufficiency >KDOKI stage III (cockroft formula);

13. Concomitant muscle disease;

14. Reumatological disorders;

15. Medication: CYP3A4-inhibitors as Ciclosporine, Itraconazol, Ketoconazol, Erytromycin, Claritromycin, HIV-protease inhibitors of grapefruit juice. Antimycotic azoolderivates or macrolide antibiotics and Gemfibrozil. Also other fibrates (PPAR-alpha), nicotine acid and fucidin acid, use of Gamma activators (Rosiglitazone, Pioglitazone, etc.) and use of anti-inflammatory agents in general.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	10-10-2011
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	31-05-2012
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	NL3309
NTR-old	NTR3456
Ander register	METC : 10-018
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A