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

No registrations found.

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

Summary

ID

NL-OMON25154

Source
Nationaal Trial Register

Health condition

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

Sponsors and support

Primary sponsor: BWJ Hellebrekers
Haga Teaching Hospital, Department of Gynecology
Leyweg 275
2545 CH The Hague
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Source(s) of monetary or material Support: BWJ Hellebrekers
Haga Teaching Hospital, Department of Gynecology
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Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Peak level in plasma of distribution FM/FbDP's;

2. Area under curve of postoperative distribution FM/FbDP's in plasma.

Study description

Background summary

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.

Study objective

Statins are able to significantly increase peritoneal fibrinolytic activity.

Study design

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.

Intervention

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

Control: Placebo.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-10-2011
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	31-05-2012
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	NL3309
NTR-old	NTR3456
Other	METC : 10-018
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A