A tampon after vaginal surgery: useful or superfluous?

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22805

Source
NTR

Brief title
N/A

Health condition

Vaginal surgery.

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

To investigate whether there are less postoperative bleeding and hematomas after vaginal surgery by using a vaginal tampon.

Secondary outcome

To investigate the effect of the use of a tampon after vaginal surgery on the number and kind of postoperative infections, the effect on prolaps surgery and the effect on the quality of life.

Study description

Background summary

The purpose of the trial is to investigate whether there is less postoperative bleeding by using a tampon after vaginal surgery, whether there are more complications like infections, whether the result of prolapse surgery is negatively influenced by not using a tampon and what kind of influence there is on the quality of life.

There will be a comparison of two randomised groups, one group will receive a vaginal tampon and the other group won't. All women who will be submitted to vaginal surgery, will be asked to cooperate.

Study objective

1. Is there, by using a vaginal tampon, less postoperative bleeding?;

2. Are there, by using a vaginal tampon, less postoperative infections?;

3. Is the result of prolapse surgery negatively influenced by not using a vaginal tampon?;

4. What kind of influence is there on the quality of life by using or not using a vaginal tampon?

Study design

N/A

Intervention

The use of a vaginal tampon in one group and no use of a vaginal tampon in the other group after vaginal surgery.

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Eligibility criteria

Inclusion criteria

All vaginal surgery, willing to cooperate.

Exclusion criteria

TVT/TOT surgery, combined abdominal-vaginal surgery.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2005
Enrollment:	150
Type:	Actual

Ethics review

Positive opinion Date:	13-09-2005
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	NL472
NTR-old	NTR513
Other	: N/A
ISRCTN	incomplete data for ISRCTN

Study results

Summary results
N/A