

Cosmo-Niveau

"Cosmetic results of choosing a different level of skin- and fascia-incision in a low transverse abdominal incision"

Published: 22-01-2008

Last updated: 11-05-2024

To determine whether there is any difference in the cosmetic result among women undergoing surgery for gynaecological diseases using two different lower transverse abdominal incisions: the Pfannenstiel incision versus a comparable technique in which...

Ethical review	Approved WMO
Status	Pending
Health condition type	Procedural related injuries and complications NEC
Study type	Interventional

Summary

ID

NL-OMON32047

Source

ToetsingOnline

Brief title

Cosmo-Niveau

Condition

- Procedural related injuries and complications NEC
- Obstetric and gynaecological therapeutic procedures

Synonym

retracted operative scar; scar cosmetics

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: incision level, laparotomy scar, scar cosmetics, transverse abdominal incision

Outcome measures

Primary outcome

Cosmetic outcome of the operative scar, judged by both an independent observer and the patient herself.

Secondary outcome

surgical convenience, pain, wound hematoma, wound infection, wound dehiscence.

Study description

Background summary

In gynaecological surgery transverse incisions are frequently used. Notwithstanding its very acceptable cosmetic result, women complain sometimes about overhanging of the skin (and subcutis) above the scar, probably caused by the retraction of the scar tissue of the fascia and of the skin in the same level, with subsequent *belly formation* above the scar.

Study objective

To determine whether there is any difference in the cosmetic result among women undergoing surgery for gynaecological diseases using two different lower transverse abdominal incisions: the Pfannenstiel incision versus a comparable technique in which the fascia incision is put 3-5 centimeters higher than the level of the skin incision.

Study design

A randomised controlled clinical trial. Both patients and independent observers are blinded for the used surgical technique.

Intervention

Apply either the classic Pfannenstiel technique when opening the abdominal cavity (control group) or an alternative technique, described in the paragraph "Objective of the study" (study group).

Study burden and risks

Patients will not experience any extra discomfort by participating in this study and, apart from the one extra visit to the outpatient clinic 6 months after the operation, it will not cost them any extra time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

All women undergoing a laparotomy for a gynecological condition through a low transversal abdominal incision

Exclusion criteria

- dark skin (because of a higher risk of hypertrophic scar tissue or keloid formation)
- having had an operation through a low transverse abdominal incision before
- pregnancy.

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	74
Type:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL19676.058.07