

Randomized controlled trial comparing Monocryl ® and Vicryl rapide ® for the subcuticular skin repair after episiotomy.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Postpartum and puerperal disorders
Study type	Interventional

Summary

ID

NL-OMON35717

Source

ToetsingOnline

Brief title

The MOVE-study.

Condition

- Postpartum and puerperal disorders

Synonym

Episiotomy

Research involving

Human

Sponsors and support

Primary sponsor: Ikazia Ziekenhuis

Source(s) of monetary or material Support: Maatschap Gynaecologie;Ikazia Ziekenhuis;Rotterdam

Intervention

Keyword: Episiotomy, Monocryl ®, Pain, Vicryl Rapide ®

Outcome measures

Primary outcome

Primary outcome is the pain score in sitting position (Visual Analogous Scale, VAS) 10 days postpartum

Secondary outcome

Secondary outcomes are pain (VAS-score) 24 hours postpartum, dyspareunia 10 days postpartum and pain and dyspareunia 6 weeks and 3 months postpartum and complications like wound dehiscence and infection.

Study description

Background summary

When an episiotomy has to be sutured following vaginal delivery, short term and long term complaints of pain and dyspareunia are frequently reported. The choice of suture material may well influence the severity and frequency of complaints and the time intercourse is resumed.

In order to minimise perineal complaints it is important to gain insight in the optimal suture material.

Synthetic soluble suture materials have been proven to be superior to natural and non-soluble materials. They exist as as braided, such as Vicryl ®/vicryl rapide ®, and as monofilaments, such as Monocryl ®. Braided materials have a larger surface area and give more friction when pulled through tissue, thereby increasing the chances of infection and increasing tissue reaction to the material. This could cause more perineal complaints when using Vicryl rapide ® then using Monocryl ®.

Monocryl ® on the other hand dissolves slower (119 days) and retains traction longer (25% after 14 days.). Vicryl rapide ® has the advantage of dissolving within a short time and losing its traction (50% force after 5 days, 0 % after 14 days) and is completely dissolved after 42 days. This could lead to more

complaints when using Monocryl ®.

To determine if the differences in properties of the suturing materials have clinical consequences such as differences in pain, dyspareunia and complications further research needs to be done.

Study objective

Objectives of this study are to determine whether Vicryl rapide ® or Monocryl ® is the optimal suture material for closing the skin in the suturing of an episiotomy. This will be done by determining pain and dyspareunia at several intervals after the episiotomy.

Study design

single blinded randomized controlled trial

Intervention

Subcuticular stitching of the skin with Monocryl ® or Vicryl rapide ® when an episiotomy has been made.

Study burden and risks

In this trial 2 stitching materials are being used with which extensive experience exists for the closure of episiotomies. Knowledge about the extent of complaints in the healing process is lacking. Patients do not run additional risks by participating in the trial. Patients will fill in the questionnaires which will take four times several minutes.

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

primiparous

uncomplicated episiotomy

Informed consent

Exclusion criteria

multiparous women

vaginal or perineal laceration other than extension of the vaginal part of the episiotomy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 22-11-2010
Enrollment: 250
Type: Actual

Ethics review

Approved WMO
Date: 07-10-2010
Application type: First submission
Review commission: TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL28922.101.10