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The MOVE-trial: monocryl versus vicryl rapide for skin repair of episiotomies: a randomised controlled trial

Submission date
15/04/2016

Recruitment status
No longer recruiting

Registration date
20/04/2016

Overall study status
Completed

Last Edited
19/05/2023

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims:
Sometimes during childbirth, an episiotomy may have to be performed to help with the delivery of the baby. An episiotomy is a cut that is made in the women's perineum (the area between the vagina and the anus). This cut makes the vagina opening wider, allowing easier delivery of the baby.
Once the child has been born, the cut is stitched together (sutured) using dissolvable stitches. Three layers of tissue have to be sutured: the vaginal wall, the muscles and the skin. In the months after the birth, some women experience pain during intercourse or even when they are going about their daily lives. Studies in the past have shown that different suture materials and different suture techniques may affect the recovery from a episiotomy. The aim of this study is to compare two often used suture materials, Monocryl and Vicryl rapide, for the suturing of the skin in women with an episiotomy after their first delivery. The patients will be asked about their experiences of pain and assessed for complications in the healing process and comparisons made to see which material is best.

Who can participate
Women over 18 years old who have an episiotomy while giving birth to their first baby.

What does the study involve?
After birth, the vaginal wall and the muscles are sutured in exactly the same way for all participants. They are then randomly allocated to one of two groups. For those in group 1, the skin is sutured using the material Monocryl. For those in group 2, the skin is sutured using Vicryl rapide. They are all asked to fill in questionnaires after 24 hours, 10 days, 6 weeks and 3 months. The results are compared after all questionnaires have been returned.

What are the possible benefits or risks of participants:
Both suture materials are often used for the suturing of the skin. No risks are associated with the participation.

Where is the study run from:
Ikazia Hospital, Rotterdam (Netherlands)

When is the study starting and how long is it expected to run
October 2010 to July 2013

Who is funding the trial
Department of Gynaecology, Ikazia hospital, Rotterdam (Netherlands)

Who is the main contact?
Mr R.G.D.Odijk, MD

Contact information

Type(s)
Public

Contact name
Mr Roeland Odijk

ORCID ID
http://orcid.org/0000-0002-9343-833X

Contact details
Amphia Hospital, Department of Obstetrics and Gynaecology
Langendijk 75
Breda
Netherlands
4819 EV

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ABR 28922

Study information

Scientific Title
Suturing of the skin using Monocryl verses suturing of the skin using Vicryl rapide in women with an uncomplicated mediolateral episiotomy after their first delivery

Acronym
MOVE

Study objectives
Deliveries are often complicated by perineal trauma. Different suture materials may give differences in complaints when used for suturing. In this trial Monocryl and Vicryl rapide were compared for complaints of pain and dyspareunia and complications such as infections and dehiscence after use for skin repair in episiotomies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Review Committee Scientific Research Rotterdam, 07/10/2010, ref: NL28922.101.10

Study design
Single centre single blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Episiotomy

Interventions
In both arms the episiotomy was sutured as follows:

The vaginal wall was sutured continuously using Vicryl rapide 2-0 from the apex to the hymen. The bulbocavernosus and superficial perineal muscles and subcutaneous tissue were sutured with interrupted stitches using Vicryl 0.

The skin was sutured intracutaneously using Monocryl 3-0 SH in one arm of the trial and using Vicryl rapide 3-0 SH in the other arm of the trial. The first knot was tied in the subcutaneous tissue at the distal end of the episiotomy. From here a continuous intracutaneous suture to the fourchette was made where a knot was tied.

Intervention Type
Procedure/Surgery

Primary outcome measure

Pain scores as measured by a Visual Analoguous Scale (VAS) when in sitting position at 10 days post partum

Secondary outcome measures
1. Pain, when walking and supine position, using VAS scores at 6 weeks, 3 months
2. Dyspareunia, using the VAS score, measured after 6 weeks, 3 months
3. Wound infections, measured at 10 days, 6 weeks, 3 months
4. Wound dehiscence 10 days, 6 weeks, 3 months
5. Percentage of patients using analgesics, measured at 24 hours, 10 days, 6 weeks, 3 months
6. Percentage of patients that have suture material removed, measured at 10 days, 6 weeks, 3 months
7. Percentage of patients resuming intercourse, measured at 6 weeks, 3 months

Overall study start date
07/10/2010

Completion date
19/07/2013

Eligibility

Key inclusion criteria
1. Episiotomy
2. Primiparous
3. Informed consent
4. Suturing occurs on the delivery room
5. Age>18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
250

Total final enrolment
250

Key exclusion criteria
1. Immune compromised patient
2. Coagulopathy or thrombocytopenia

3. Existence of ruptures other than ipsilateral vaginal wall rupture that require suturing and may cause additional complaints of pain
4. Haemorrhage requiring fast intervention
5. Inadequate understanding of the Dutch language

Date of first enrolment
15/11/2010

Date of final enrolment
19/07/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
Ikazia Hospital
Montessoriweg 1
Rotterdam
Netherlands
3083 AN

Sponsor information

Organisation
Ikazia Hospital, Department of Obstetrics and Gynaecology

Sponsor details
Montessoriweg 1
Rotterdam
Netherlands
3083 AN

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01abkkw91

Funder(s)

Funder type

Not defined

Funder Name
Ikazia Hospital, Department of Obstetrics and Gynaecology

Results and Publications

Publication and dissemination plan
The intention is to write a full report of the randomised controlled trial with its results and publish it in the summer of 2016.

Intention to publish date
30/06/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/10/2017	30/11/2020	Yes	No
Dataset		16/10/2017	19/05/2023	No	No