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Does adding myofascial release (a type of soft tissue manipulation) to silicone patches improve Caesarean scar healing more than using silicone patches alone?

Submission date
09/12/2019

Recruitment status
No longer recruiting

Registration date
20/12/2019

Overall study status
Completed

Last Edited
20/12/2019

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims:
Caesarean sections are increasingly used to deliver babies. In Poland about 40% of deliveries end in a C-section. Caesarean scar healing can require targeted actions to reduce tightness and pulling and separate it from surrounding tissues. Silicone patches have been shown to improve scar healing. This study aims to investigate whether manipulation of the skin and tissues around the scar, similar to massage, can improve healing still further.

Who can participate?
Women aged 18-45 after Caesarean section (within 6-12 weeks after the delivery)

What does the study involve?
Participants will be randomly allocated into one of two groups. Both groups will use silicone patches on the Caesarean scar. One group will also receive manual therapy treatment from a therapist once a week for 8 weeks and be shown how to repeat the treatment themselves at home. The scar and associated pain will be assessed before treatment, 1 month after treatment and 6 months after treatment.

What are the possible benefits and risks of participating?
Participants might benefit from learning more about their scar and how to encourage it to heal. They will all receive treatment that has been shown to improve scar healing. There are no side effects of the planned treatment.

Where is the study run from?
Opole Medical School (Poland)

When is the study starting and how long is it expected to run for?
October 2018 to April 2022

Who is funding the study?
Opole Medical School (Poland)

Who is the main contact?
Dr Lucyna Ptaszkowska, ptaszkowska.l@gmail.com

Study website
http://wsm.opole.pl/3210/5723/projekty-badawcze.html

Contact information

Type(s)
Scientific

Contact name
Dr Lucyna Ptaszkowska

ORCID ID
http://orcid.org/0000-0002-7706-0971

Contact details
Opole Medical School
Katowicka 68
45-060 Opole
Opole
Poland
45-060
+48 695401515
ptaszkowska.l@gmail.com

Type(s)
Public

Contact name
Dr Malgorzata Pasternok

ORCID ID
http://orcid.org/0000-0002-5642-6436

Contact details
Opole Medical School
Katowicka 69
Opole
Poland
45-060
+48 506174008
pasmal@wp.pl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
KB/92/FI/2018

Study information

Scientific Title
The effect of selected therapeutic (myofascial relaxation techniques and silicone patches) interventions on the biomechanical properties of scar tissue after Caesarean section

Study objectives
1. Assessment of biomechanical properties of scar tissue within the scar after Caesarean section depending on the therapeutic intervention used (myofascial release techniques and silicone patches).
2. Assessment of improvements in Vancouver Scar Scale (VSS) and pain reduction (VAS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/10/2018, Opole Medical School Bioethics Commission (Katowicka 68, 45-060 Opole, Poland; +48 774410882; sekprorek.ds.nauk@wsm.opole.pl), ref: KB/92/FI/2018

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied

Scarring after Caesarean section

Interventions
Participants will be randomly assigned to one of two comparison groups. Randomization using a 1:1 randomization scheme will be carried out using computer-generated random numbers (simple randomization).

The therapy programme lasts 8 weeks during which all the participants receive the silicone patches to promote scar healing. In addition, women assigned to one of the groups will undergo manual therapy treatment consisting of 8 meetings with a qualified physiotherapist (once a week). They will also repeat the manual techniques themselves at home.

The manual scar therapy procedure based on myofascial relaxation techniques consists of techniques such as:
1. Overall stretching technique - 5 min
2. Technique of delicate circles - 5 min
3. Up and down stretching movements in the shape of the letter J - 5 min
4. Vertical lifting technique - 5 min
5. Skin rolling - 5 min
6. S-shaped technique - 5 min

All participants will undergo assessment of the biomechanical properties of the scar area before the start of treatment, 1 month after and 6 months after the therapy programme.

Intervention Type
Mixed

Primary outcome measure
1. Scar tissue tone assessed using the MyotonPRO digital palpation device before the start of the intervention, immediate after the end of the intervention and 1 month and 6 months after the end of the intervention
2. Scar tissue stiffness assessed using the MyotonPRO digital palpation device before the start of the intervention, immediate after the end of the intervention and 1 month and 6 months after the end of the intervention
3. Scar tissue elasticity assessed using the MyotonPRO digital palpation device before the start of the intervention, immediate after the end of the intervention and 1 month and 6 months after the end of the intervention

Secondary outcome measures
1. Scar severity (comprising vascularity, height/thickness, pliability, and pigmentation) assessed using the Vancouver Scar Scale before the start of the intervention, immediate after the end of the intervention and 1 month and 6 months after the end of the intervention
2. Scar pain assessed using a visual analogue scale (VAS) before the start of the intervention, immediate after the end of the intervention and 1 month and 6 months after the end of the intervention

Overall study start date
01/10/2018

Completion date
01/04/2022

Eligibility

Key inclusion criteria
1. Women after Caesarean section within 6 weeks of surgery (transverse cut using the Pfannenstiel method)
2. Full healing of the wound after the scab falls off
3. Healthy on the day of the test
4. End of the puerperium period
5. Aged 18-45 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
60

Key exclusion criteria
1. Caesarean section was less than 6 weeks or more than 12 weeks previously
2. Incomplete wound healing (exudate, local inflammation)
3. Malaise on the day of the test
4. Caesarean section in multiple pregnancies
5. Lack of consent of the examined person

Date of first enrolment
15/01/2020

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
Poland

Study participating centre

Opole Medical School
Katowicka 68 Street
Opole
Poland
45-060

Sponsor information

Organisation
Opole Medical School

Sponsor details
Katowicka 68
Opole
Poland
45-060
+48 (0)774423546
snw@wsm.opole.pl

Sponsor type
University/education

Website
http://wsm.opole.pl/1/strona-glowna.html

ROR
https://ror.org/000bjk220

Funder(s)

Funder type
University/education

Funder Name
Państwowa Medyczna Wyższa Szkoła Zawodowa w Opolu [Opole Medical School]

Results and Publications

Publication and dissemination plan
Planned for publication in a high-impact peer-reviewed journal.

Intention to publish date

30/12/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary

Available on request