EPIPAIN trial: Radiofrequency therapy at 448 kHz for persisting pain after episiotomy - a feasibility study

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To evaluate the feasibility of MCRRF therapy in women with persisting perineal pain after episiotomy. Collection of pilot data is essential in the preparation of a larger randomized-controlled trial that investigates the efficacy of MCRRF therapy.

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

Summary

ID

NL-OMON51475

Source
ToetsingOnline

Brief title
EPIPAIN

Condition

- Postpartum and puerperal disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
episiotomy, vaginal cut

Research involving
Human

Sponsors and support

Primary sponsor: Ikazia Ziekenhuis
Source(s) of monetary or material Support: Indiba,Indiba, S.A.

Intervention

Keyword: 448 khz, episiotomy, pain, radiofrequency

Outcome measures

Primary outcome

The primary endpoint the feasibility of a trial with MCRRF therapy in women with persisting perineal pain after episiotomy. Feasibility will be assessed by recruitment, retention and satisfaction.

Secondary outcome

The secondary endpoint is to explore the potential pain-reducing effects of MCRRF therapy using VAS scores.

Study description

Background summary

Episiotomy is the most frequently performed operative procedure during delivery. Perineal pain after episiotomy usually resolves within a few weeks, but 13-23% of the women still report pain symptoms 6 weeks after delivery. There is limited information about the management of persisting pain after episiotomy. Recent research shows promising results of Monopolar Capacitive Resistive Radiofrequency (MCRRF) therapy at 448 kHz in the treatment of various chronic pain conditions. We hypothesize that MCRRF therapy is a possible treatment modality for women with persisting pain in the pelvic floor region after episiotomy.

Study objective

To evaluate the feasibility of MCRRF therapy in women with persisting perineal pain after episiotomy. Collection of pilot data is essential in the preparation of a larger randomized-controlled trial that investigates the efficacy of MCRRF therapy.

Study design

An exploratory, prospective single-arm single-centre trial

Intervention

All participants receive a total of 7 MCRRF session treatments at a rate of 1 session per week.

Study burden and risks

Patients enrolled in this study will receive a total of 7 MCRRF session treatments, at a frequency of 1 session per week. Before and after the intervention, subjects are asked to complete a questionnaire including pain scores. MCRRF therapy is considered safe and is already used in a variety of chronic pain conditions, with no serious risks reported in literature. Furthermore, the reported risks, such as skin irritation and superficial burns, are minimal when the therapy is given by certified pelvic physiotherapists.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (16-17 years)

Adults (18-64 years)

Inclusion criteria

1. Age > 18 years
2. Persisting pain in the pelvic floor region (VAS-score > 4) after a mediolateral episiotomy
3. At least 6 weeks after delivery

Exclusion criteria

1. Signs of infection of the episiotomy wound
2. Pacemaker or other electronical implant
3. Nickel allergy
4. Pregnancy

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2023
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Activ AT7 (Radiofrequency Hyperthermia Unit)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-12-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL81426.100.22