Remote ischemic preconditioning for pain management in labour: a randomized controlled pilot study.

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Reduce the need for other analgesia after RIPC by investigating the efficacy of remote ischemic preconditioning on pain during labour.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45643

Source
ToetsingOnline

Brief title
Remote ischemic Preconditioning and labour pain

Condition

- Other condition
- Pregnancy, labour, delivery and postpartum conditions

Synonym
labour pain

Health condition

pijn

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Labour, Pain, RIPC

Outcome measures

Primary outcome

The time between the intervention and the need for any (other) analgesia.

Secondary outcome

• Women with 30% or more pain relief after 10 minutes, 30 minutes, one hour and

then every hour after treatment

• NRS scores and analgesic needs

• Rate of assisted vaginal birth

• Rate of caesarean section

• Apgar score

• Significant maternal morbidity; major postpartum haemorrhage, uterine

rupture, admission to an ICU, eclampsia or severe HELLP

• Adverse and serious adverse events

Study description

Background summary

Remote ischemic preconditioning as a non-invasive, non-pharmacological method for pain relief during labour.

Study objective

Reduce the need for other analgesia after RIPC by investigating the efficacy of remote ischemic preconditioning on pain during labour.

Study design

Randomized, single blinded, placebo controlled, pilot intervention study

Intervention

Randomization creates 2 groups. One group will undergo 3 cycles of ischemia for 5 minutes (50 mmHg above own systolic blood pressure) followed by 5 minutes of reperfusion. In the other group the tourniquet pressure is 20 mmHg with the same 3 cycles and this is the control group.

Study burden and risks

Participation involves 3 times 5 minutes or tourniquet pressure. There is no risk associated with participation. Registration of NRS scores is routine practice in accordance the VMS-criteria. Women are free to ask for regular analgesics for pain management.

Contacts

Public
Selecteer

Philips van Leydenlaan 25
Nijmegen 6525 EX
NL
Scientific
Selecteer

Philips van Leydenlaan 25
Nijmegen 6525 EX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Woman at 37-42 gestational weeks
• Aged > 18 years

Exclusion criteria

• Analgesics before study
• Raynaud phenomenon
• Post-traumatic lengthy hand reconstruction on both upper extremities
• Severe crushing injuries on both upper extremities
• Skin grafts on both upper extremities
• Patients with advice for epidural analgesia
• Patient with contraindications for epidural analgesia
• Obstetrical complications such as:
o Intrauterine fetal death
o Obstetric high care patient
o Bleeding disorders
o Thrombosis disorders

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-08-2018
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Pneumatic tourniquet
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	26-09-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21798
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL61233.091.17
OMON	NL-OMON21798