The influence of mobilisation of the sacroiliacal joint and an stabilizing or relaxation exercise program on pain, the function of the pelvic floor, the m. Transversus Abdominus and functional state in patients with pelvic girdle pain.

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

Summary

ID

NL-OMON53037

Source
ToetsingOnline

Brief title
Usual care in pelvic physiotherapy in patients with pelvic girdle pain

Condition

- Joint disorders
- Pregnancy, labour, delivery and postpartum conditions

Synonym
pelvic girdle pain, pelvic pain

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: subsidie is aangevraagd bij de Nederlandse Vereniging voor Manuele Therapie (NVMT)

Intervention

Keyword: Electromyography, pelvic floor, pelvic girdle pain, questionnairres

Outcome measures

Primary outcome

Changes in the score on the NPRS

Secondary outcome

Changes in the EMG signals of the pelvic floor

Measuring results of the VBA forward and lateral

Changes in the PeLFIs, PSK and QPBDS

Changes in ultrasound

Study description

Background summary

Low back pain (LBP) and pelvic girdle pain (PGP) during and after pregnancy is common in the Netherlands. The point prevalence in women with a history of LBP/PGP is 88,5% during pregnancy, which decreases to 53,8% two weeks after delivery.
In woman without such a history is the point prevalence 67,4 during pregnancy decreasing to 28,1 % two weeks after delivery (1).
The incidence of PGP during pregnancy is 20,1%. In 62,5 % of this group the pain disappeared within a month after delivery. Two years after delivery 8,6 % of the women still had PGP (2,3)

PGP during pregnancy gives often problems in daily life and absenteeism of work

(4).
Risk factors are: a history of LBP and/or a trauma of the pelvis in the past. There is conflicting evidence (one study) for multiparous and high pressure at work (5)

Despite the quantity of research, diagnosis and classification of PGP is controversial. There has been no clear pathological anatomical explanation for most of the pelvic diseases so far(6).
The concept version of the European Guidelines on the diagnosis and treatment of Pelvic Girdle Pain (5) mentions a consensus definition of PGP: * Pelvic girdle pain (PGP) generally arises in relation to pregnancy, trauma, osteo-arthrosis and arthritis. Pain is experienced between the posterior iliac crest and the gluteal fold, particularly in the vicinity of the sacroiliac joints (SIJ). The pain may radiate in the posterior thigh and can also occur in conjunction with/or separately in the symphysis. The endurance capacity for standing, walking, and sitting is diminished.*
The diagnosis of PGP can be reached after exclusion of lumbar causes. The pain or functional disturbances in relation to PGP must be reproducible by specific clinical tests, such as the Active Straight Leg Raise (ASLR) and the Posterior Pelvic Pain Provocation (PPPP)-test *

O*Sullivan and Beales describe a hypothetic *mechanism based* classification system within a bio psychosocial framework. According to them the classification system helps choosing the right treatment. Within the group a specific PGP disorders they distinguish following subgroups: centrally induced PGP and peripherally induced PGP.
Centrally induced PGP is commonly associated with extended, severe and constant pain that is non-mechanical in nature. These disorders are often associated with dominant psychosocial factors.
Peripherally mediated (mechanically induced) pelvic girdle pain disorders may be classified into two clinical subgroups: the excessive force closure (excessive activation of the motor system local to the pelvis) and the reduced force closure (a loss of functional patterns of co-contraction of the local force closure muscles of the pelvis)

The excessive force closure group is commonly associated with a negative ASLR. Compression (manual or using a Sacro Iliacal Joint belt), is often provocative, as is local muscle activation (pelvic floor, transverse abdominal wall, back muscles, iliopsoas, gluteal muscles). They commonly hold habitual erect lordotic lumbopelvic postures associated with high levels of co-contraction across various of the muscles mentioned above.
The reduced force closure group are commonly associated with a positive ASLR test (normalised with pelvic compression). Loss of functional patterns of the pelvic floor, the transverse abdominal wall, the lumbar multifidus, iliopsoas and the gluteal muscles. Their primary functional impairments are associated with pain in weight bearing postures such as sitting, standing, walking and

cycling. Postures such as *sway* standing, *hanging off one leg*, *slump* sitting are often seen.

The *selflocking-mechanism* is a combination of force closure and form closure. Nutation of the sacrum enhances the form closure and contributes to stability (7).
There is little research done treatment of PGP.
The concept guidelines advise an individual training program, emphasizing and starting with activation and control of local deep lumbopelvic muscles. Gradually include the training of more superficial muscles in dynamic exercises to improve control mobility, strength, and endurance capacity. This program is for the reduced forceclosure. Little research has been conducted to the effect of manipulation with mobilisation with PGP.

Reducing of the force closure is advised for the subgroup excessive force closure trough relaxation and cardiovascular exercise (6) From clinical experience this approach appears very effective although clinical studies are required to validate this.

In our clinic we see patients with PGP on a regular basis. From clinical experience the combination of a mobilisation and an stabilizing or relaxing exercise program of local and global muscles looks promising. Therefore , it*s very important to substantiate this scientifically.

The goal of this study is to investigate the effect of a pelvic physiotherapeutic / manual therapeutic treatment (usual care) in patients with PGP (subgroups reduced force closure and excessive force closure)and the influence on EMG signals of the pelvic floor

Study objective

The influence of mobilisation of the sacroiliacal joint and an stabilizing or relaxation exercise program on pain, the function of the pelvic floor, the m. Transversus Abdominus and functional state in patients with pelvic girdle pain.

Study design

This is a longitudinal study in which patients with pelvic pain, subgroups reduced and excessive force closure, receiving a usual care pelvic physiotherapeutic / manual therapeutic treatment (mobilization of the sacral iliac joint and a stabilizing or relaxing exercise program) are followed.

Design:
Randomized Controlled Trail with two groups, an intervention group and a

control group.
The intervention group gets alongside a stabilizing or relaxing exercise program and mobilization of the sacral iliac joint. The control group will receive a stabilizing or relaxing exercise program during the first 6 weeks. After 6 weeks, they also receive the mobilization of the sacral iliac joint. The patients are randomly divided over the two groups.

This study will consist of 5 parts:

1. Questionnaires. With the validated questionnaires Pelvic Floor Inventories Leiden (8.9), Quebeck Back Pain Disability Scale (QBPDS) (10), Numeric Pain Rating Scale (NPRS) (11) Patient Specific Questionnaire (PSK) (12) is included in this patient group The complaints in the pelvic region and the functional status mapped
2. Provocation tests: With the validated challenge test ASLR and PPPP test, the subgroup is mapped in this patient group (5, 16, 17).
3. Physical examination: With the Fingerfloor Distance Forward(VBA) (Forward bending with stretched and closed legs. Measuring distance finger floor) and sideways (Sideways bending with Stretched and Closed Legs. Measuring distance Floor Finger) and Jointplay (joint mobility) research, the function of the sacro iliac joints (SIG) is mapped in this patient group
4. Multiple Array Probe Leiden (MAPLe) (14): With the validated MAPLe, the function of the pelvic floor in this patient group is mapped through EMG
5. Ultrasound: With Ultrasound, the function of the MTrA is mapped in this patient group

Intervention

Mobilization of the functional disorder of the sacral iliac joint and a stabilizing or relaxing exercise program.

Study burden and risks

Intake: interview, 4 questionnaires, physical examination
Intake (continued): intra vaginal EMG examination with vaginal probe, ultrasound (external)
3x Evaluation: 4 questionnaires, physical examination,intra vaginal EMG examination with vaginal probe, ultrasound (external)

The intra vaginall EMG examination obtains the function of the pelvic floor in an objective manner (Usual Care), and the ultrasound obtains an objective view of the function of the transverse abdominal muscle. This contributes to the determination of the subgroup in wich the patient belongs in order that the appropriate intervention can be applied. By interpretation of the results of the intravaginall EMG and ultrasound in time, one can analyze and interpret

the effect of the intervention on the pelvic floor and the transverse abdominal muscle.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

patients with pelvic girdle pain pre- and postpartum

Exclusion criteria

Adherence
Not aible to speak or read Dutch
Sacroiliitis,

History of fractures, neoplasms and / or surgery,in the lumbar spine, pelvis or hip
radiculopathy
> 30 weeks pregnant

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2018
Enrollment:	46
Type:	Actual

Ethics review

Approved WMO Date:	15-05-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	26-08-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	15-01-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	11-03-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	31-08-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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: 26047
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL57765.058.17

Register	ID
OMON	NL-OMON26047

Study results

Date completed:	09-02-2023
Actual enrolment:	52