

Peripartum pelvic pain during pregnancy and after delivery. A cohort and intervention study

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| Submission date 18/11/2004 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 20/12/2004 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 06/06/2008 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PPBS-study

Study information

Scientific Title

Acronym

PPGP - Peri-partal Pelvic Girdle Pain (PPBS - Peri Partaal Bekkenpijn Syndroom)

Study objectives

Pregnancy-related pelvic girdle and/or low back pain is a syndrome with an onset during pregnancy, characterized by pain in the lumbar-pelvic region and feelings of instability when standing and walking. After delivery most symptoms subside, but some women report persisting pain and a small group do not develop complaints until after delivery. Often symptoms have an impact on activities of daily life, participation in society and sometimes lead to a chronic disabling condition with considerable work absenteeism in the future.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Peripartum pelvic pain

Interventions

Experimental intervention: Theoretical concepts of self-management and fear-avoidance were integrated in the treatment protocol. It is an individualized approach of 7-9 sessions with a frequency of once a week. Standardized information is presented through a treatment protocol for the therapists and booklets for the patients. Generally, a time contingent policy is followed in which women set the pace.

Usual care: A pain contingent regimen of relative (bed) rest and avoiding and limiting several day-to-day activities. Goal setting focused on disease management with an accent on biomedical factors.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Primary domain for improvement of the intervention was limitations in activities. Other important domains were the severity of the main complaint and global feeling of recovery.

Secondary outcome measures

Pain was measured with two Visual Analog rating Scales (VAS) of the McGill Pain Questionnaire (MPQ-DLV) to record the intensity of pain the last week and day.

The impact on participation and autonomy (IPA) measured person-perceived restriction in participation and autonomy. The used subscales were self-care and appearance, mobility, leisure, social relationships and family role. Perceived participation is graded on a 5-point rating scale ranging from 0 (very good) to 4 (very poor).

Fear of movement was measured by the Dutch translation of the Tampa Scale for Kinesiophobia (TSK). We used the TSK and the both subscales 'fear avoidance' and 'harm'.

The Short-Form 36 (SF-36) evaluated health status. We used the subscale 'general health'.

Overall study start date

01/01/2001

Completion date

30/06/2005

Eligibility

Key inclusion criteria

The trial is embedded in a cohort study (n = 7526) that is designed as a longitudinal, prospective study which studies the prevalence, etiology, severity and prognosis during pregnancy until 1 year after delivery. Participants are included in the cohort when they are at least 18 years old, pregnant (about 14 weeks) and well versed in the Dutch language. Women are included in the intervention study out of the cohort at the time of three weeks after delivery.

Inclusion criteria are: pain in the pelvic girdle and/or low back pain with an onset during pregnancy and a delay in recuperation. The frame of reference for the inclusion criteria is a random sample of 100 women out of the cohort without complaints, examined with the same protocol three weeks after delivery.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

127

Key exclusion criteria

Women diagnosed with a relevant specific pathology are excluded.

Date of first enrolment

01/01/2001

Date of final enrolment

30/06/2005

Locations**Countries of recruitment**

Netherlands

Study participating centre**Department of Epidemiology**

Maastricht

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Sponsor information**Organisation**

Dutch Health Care Insurance Board (College Voor Zorgverzekeringen) (The Netherlands)

Sponsor details

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Sponsor type

Government

Funder(s)**Funder type**

Government

Funder Name

Dutch Health Care Insurance Board (College voor Zorgverzekeringen) (PPBS-study)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|--------------------|--------------|------------|----------------|-----------------|
| Protocol article | Protocol | 24/12/2004 | | Yes | No |
| Results article | Short-term results | 27/02/2006 | | Yes | No |
| Results article | Long-term results | 30/05/2008 | | Yes | No |