ISRCTN13438272 https://doi.org/10.1186/ISRCTN13438272

Effects of a new mattress and pillow for nightly pelvic girdle pain during pregnancy

Submission date
20/04/2018

Recruitment status
No longer recruiting

Registration date
27/04/2018

Overall study status
Completed

Last Edited
20/12/2021

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Three out of ten pregnant women experience pelvic girdle pain (PGP) and one of ten experiences severe pain. Many of these women have difficulties finding a pain-free sleeping position. This can result in frequent awakenings during the night and daytime tiredness.
A newly developed mattress and pillow have been specially designed for patients with sleep apnea (breathing problems when asleep) so that they avoid sleeping on their back and can achieve a comfortable sleeping position on their side. The newly developed mattress and pillow consists of stretchy foam that shapes around the body. The pillow is separated from the mattress, resulting in a unique possibility to support the shoulder and pelvis when sleeping on the side.
The aim of this study is to investigate whether this mattress and pillow, when added to standard treatment, can decrease nightly pain and sick leave, improve daily function, sleep quality, subjective sleeping time and quality of life, and influence thoughts about pain in pregnant women with PGP.

Who can participate?
Pregnant women with moderate or severe nightly PGP

What does the study involve?
An independent specially-trained physiotherapist will assess patients who are eligible and willing to participate in the study. This assessment will include a physical examination and filling out questionnaires. All randomized participants will receive standard treatment at the first visit. Standard treatment consists of general information about the condition and anatomy of the back and pelvis. Advice is given on the participant's activities of daily living as well as exercises to do at home that are designed to increase strength in the abdominal (lower body) and gluteal (buttock) muscles. Both groups will be offered the mattress and pillow. Group 1 (the control group) can use the mattress and pillow after 4 weeks of standard treatment alone and group 2 (the intervention group) can use them in addition to standard treatment from the start of the study. Women who are satisfied with the mattress and pillow can borrow them through their pregnancy. The same self-assessed questionnaires of pain, function, sleep quality, subjective sleeping time, sickness leave, quality of life and thoughts about pain will be re-done after 4 and 8 weeks.

In a sub-study, sleep quality will be investigated in some of each group using polysomnography (sleep tracking).

What are the possible benefits and risks of participating?
Possible benefits of participating in the study are that all women get additional treatment as well as standard treatment and that women who are satisfied with the mattress and pillow can borrow them through their pregnancy. It has been confirmed in earlier studies as well as in clinical practice that there are no side effects reported of sleeping with this mattress and pillow. A possible risk is that the exercises that the women do at home can give short-lasting pain.

Where is the study run from?
Sahlgrenska University Hospital in Gothenburg, Sweden

When is the study starting and how long is it expected to run for?
March 2018 to June 2020

Who is funding the study?
The Healthcare Board, Region Västra Götaland (Sweden)

Who is the main contact?
Professor Helen Elden
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Contact information

Type(s)
Scientific

Contact name
Prof Helen Elden

Contact details
Sahlgrenska University hospital/ East hospital
Gothenburg
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41650

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
VGRFOU-242761

Study information

Scientific Title
Effects of a new mattress and pillow as adjunct to standard treatment for nightly pelvic girdle pain in pregnant women: a randomised controlled study

Acronym
N/A

Study objectives
Null hypothesis: there is no difference in pelvic girdle pain (intensity on a visual analogue scale) in pregnant women after 4 weeks of standard treatment alone and pelvic girdle pain (intensity on a visual analogue scale) in pregnant women after 4 weeks of sleeping on a newly developed mattress and pillow as adjunct to standard treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional ethical review board in Gothenburg, 05/03/2018, 100-18

Study design
Randomized controlled cross-over multicenter trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Home

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Pelvic girdle pain (PGP) in pregnant women

Interventions
An independent specially-trained physiotherapist will assess patients who are eligible and willing to participate in the study. This assessment will include a detailed standardized physical examination and collection of baseline data through self-assessment questionnaires. All randomised participants will receive standard treatment at the inclusion visit. Standard treatment consists of general information about the condition and anatomy of the back and pelvis. Adequate advice and practice are also given with respect to the participant's activities of daily living as well as home programme exercises designed to increase strength in the abdominal and gluteal muscles. The newly developed mattress and pillow consists of viscoelastic foam,

which shapes around the body. The pillow is separated from the mattress, resulting in a unique possibility to offload the shoulder and pelvis and receive a comfortable sleeping position in a lateral position. Both groups will be offered the mattress and pillow. Group 1 after 4 weeks of standard treatment alone and group 2 (intervention group) as adjunct to standard treatment after randomisation at the inclusion visit. Women who are satisfied with the mattress and pillow can borrow them through their pregnancy. The same assessment and self-assessed questionnaires of pain, function, sleep quality, subjective sleeping time, sickness leave, quality of life and thoughts about pain will be evaluated after 4 and 8 weeks.
In a sub study, sleep quality will be investigated in a sub-group of the participants (10 from each group) using polysomnography.

Intervention Type
Device

Primary outcome measure
Current primary outcome measure as of 15/09/2021:
Intensity of nightly pelvic girdle pain measured on a 100-point visual analogue scale (VAS) every morning for the 8 week trial period

Previous primary outcome measure as of 18/03/2021:
Participant's score of the intensity of their nightly pelvic pain on a 100-point visual analogue scale (VAS), every morning and their present pelvic pain every evening in a diary

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Previous primary outcome measure:
Participant's score of the intensity of their present pelvic pain on a 100-point visual analogue scale (VAS), every morning and every evening in a diary

Secondary outcome measures
1. The Swedish version of the Pelvic Girdle Questionnaire (PGQ), a questionnaire specific for pelvic girdle pain in pregnancy
2. EuroQoL questionnaire measuring health function and health-related quality of life
3. Pain catastrophizing scale (PCS) a questionnaire measuring thoughts about pain
4. Epworth sleepiness scale (ESS) and subjective sleeping time (number of hours)
All questionnaires will be filled at baseline, 4 and 8 weeks.

Sleep registration (polysomnography) will be performed during 2-3 nights in 20 participants (10 in each group)

Overall study start date
23/03/2018

Completion date
15/06/2020

Eligibility

Key inclusion criteria
1. Otherwise healthy
2. Pregnant with singleton fetus and have completed 12-30 gestational weeks

3. Well integrated in the Swedish language
4. Pregnancy-related PGP according to the European Guidelines of diagnosis and treatment of PGP
5. Mean self-reported evening pain intensity of ≥40 mm (on a VAS) in their baseline diary, i.e. 5-7 days before the screening visit

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
70

Total final enrolment
66

Key exclusion criteria
Other pain conditions

Date of first enrolment
15/04/2018

Date of final enrolment
03/03/2020

Locations

Countries of recruitment
Sweden

Study participating centre
Sahlgrenska University hospital
Gothenburg
Sweden
S-413 45

Study participating centre
Womens health clinic in Partille
Partille
Sweden
S-433 23

Study participating centre
Womens health clinic in Gråbo
Gothenburg
Sweden
S-443 42

Sponsor information

Organisation
The Healthcare Board, Region Västra Götaland (Hälso- och sjukvårdsstyrelsen)

Sponsor details
Regionens Hus
Göteborg
Sweden
405 44

Sponsor type
Research council

ROR
https://ror.org/00a4x6777

Funder(s)

Funder type
Not defined

Funder Name
The Healthcare Board, Region Västra Götaland (Hälso- och sjukvårdsstyrelsen)

Results and Publications

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

Intention to publish date
01/06/2021

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2021	20/12/2021	Yes	No