

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

<b>Submission date</b> 20/04/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/04/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/12/2021	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> 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

[helen.elden@gu.se](mailto:helen.elden@gu.se)

## Contact information

### Type(s)

Scientific

### Contact name

Prof Helen Elden

### Contact details

Sahlgrenska University hospital/ East hospital  
Gothenburg  
Sweden  
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  $\geq 40$  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?
<a href="#">Results article</a>		01/12/2021	20/12/2021	Yes	No