ISRCTN30566933 https://doi.org/10.1186/ISRCTN30566933

Craniosacral therapy as a complement to standard treatment for the treatment of well-defined pelvic girdle pain in pregnant women

Submission date 04/06/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/09/2009	**Overall study status** Completed	
Last Edited 27/08/2013	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
VGFOUREG-26671

Study information

Scientific Title
Craniosacral therapy as a complement to standard treatment for the treatment of well-defined pelvic girdle pain in pregnant women: a randomised single-blind controlled trial

Study objectives
Null hypothesis: there is no difference in efficacy of craniosacral therapy (CST) as a complement to standard treatment and standard treatment alone for the treatment of pelvic girdle pain (PGP) in pregnant women.

Alternative hypothesis: there is a difference in efficacy of CST as a complement to standard treatment and standard treatment alone for the treatment of PGP in pregnant women.

Qualitative study:
As of 09/02/2010 this record was updated to include details of a qualitative study that will start on the 1st March 2010. All details of this qualitative study can be found in the relevant sections under the above title.

The aims of the qualitative research in the project are to describe the women's and their partners lifeworld experiences about living with PGP during pregnancy and to describe the women's and their partners experiences of CST for PGP.

The target numbers of participants for the qualitative study are 15 patients, who will receive standard treatment plus CST, and their partners.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Committee in Gothenburg approved on the 15th May 2009 (ref: 099-09)

Qualitative study:
Regional Ethics Committee in Gothenburg approved the qualitative part of the study on the 1st Jan 2010 (ref: 703-09) and the amendment of the trial 11/03/2011.

Study design
Single-blind randomised controlled interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Pelvic girdle pain

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 standardised physical examination and collection of baseline data. The tests that will be used are the posterior pelvic pain provocation test, the active straight leg test, Patrick's or FABERE test, a modified Trendelenburg's test, Lasegue test, ASLR -test (Active Straight Leg-test) and palpation of the symphysis pubis.

The study will comprise a one-week baseline period, eight weeks of treatment and follow up of the independent examiner within one week after the last treatment. All participants will get standard treatment. Standard treatment consists of general information about the condition and anatomy of the back and pelvis. Adequate advice and practice are given with respect to patient activities of daily living. The physiotherapist makes sure that the patient understands and respects the relationship between impairment, load demand, actual loading capacity, and importance of necessary rest. The purpose of this information is to reduce fear and to enable patients to become active in their own treatment. The patients will get a pelvic belt (Puff Igång AB, Sweden) and home programme exercises designed to increase strength in the abdominal and gluteal muscles.

The patients will be randomised to one of two interventions:
Group 1 will get standard treatment plus five CST sessions for eight weeks
Group 2 will get standard treatment alone for eight weeks

Qualitative study:
Initially, we will recruit 15 women receiving CST and their partners. If needed, more participants will be recruited. We will use open-ended interviews to collect the data. The interviews will take place during the last 4 weeks of treatment. The women will be asked to describe their everyday life before onset of PGP, their thoughts and experiences related to onset of PGP, their experiences of bodily changes, their experiences with healthcare professionals, their experiences with their families in their home environment, their thoughts and wishes about the future and their experiences of receiving CST.

The partners will be encouraged to describe their lived experiences regarding everyday life with the pregnant partner before onset of PGP, thoughts and experiences related to onset of PGP, experiences of their partners bodily changes due to PGP, experiences with healthcare professionals, i.e., information and treatment for PGP and experiences with the women in their home environment, and thoughts and wishes about the future. And their experiences of CST for PGP. The interviews will last about 60 minutes and will be tape-recorded. All interviews will be transcribed verbatim. Pilot interviews will be conducted to evaluate the interview questions. The data will be analysed using phenomenological analysis.

Added 12/04/2011:
The women and their partners will be re-interviewed after delivery. The same questions will be asked. Thus, the women will be asked to describe how they experienced PGP during their

pregnancies, their thoughts and wishes about the future and their experiences of receiving CST. Consequently, the partners will be asked to describe their lived experiences regarding everyday life with their pregnant partner, and thoughts and wishes about the future. And their opinions of CST for PGP.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Patient scores the intensity of their present pelvic pain in relation to motion on a 100-point visual analogue scale (VAS) every morning and every evening in the diaries.

Secondary outcome measures
1. Function (Oswestery and Disability Rating Index [DRI] will be measured before screening and at follow-up within one week after end of treatment
2. Health functioning (EuroQoL questionnaire) will be measured at screening and at follow-up within one week after end of treatment
3. Discomfort of PGP on a 100-point visual analogue scale (VAS) will be measured at screening and at follow-up within one week after end of treatment
4. Recovery from symptoms as assessed by an independent examiner will be measured at follow-up within one week after end of treatment
5. Every week during the study, the patient is asked if she has been sicklisted during the past week (yes or no). If the answer is yes, a note is then taken on the percentage of times the patient has been sicklisted, either 25%, 50%, 75% or 100% .
6. (Amended 12/04/2011) Open-ended interviews will be conducted with some of the women and their partners during the treatment period. and after delivery. This part of the study will be focused of the womens experiences of living with PGP and their experience of getting CST. Their partners will be interviewed of their experiences of living with a women with PGP.They will be re-interwieved after delivery. Then the women will be asked to describe how they experienced PGP during their pregnancies, and their experiences of receiving CST. Consequently, the partners will be asked to describe their lived experiences regarding everyday life with their pregnant partner, and their opinions of CST for PGP.
7. Credibility of the interventions will be evaluated after two weeks of treatment. An item adapted from previous literature will be used.

Previous secondary outcome measure:
6. Open-ended interviews will be conducted with some of the women and their partners during the treatment period. This part of the study will be focused of the womens experiences of living with pelvic girdle pain and their experience of getting cranio-sacral therapy. Their partners will be interviewed of their experiences of living with a women with pelvic girdle pain.

Overall study start date
24/08/2009

Completion date
15/08/2010

Eligibility

Key inclusion criteria
1. Healthy women with singleton fetuses who have completed between 12 - 28 weeks of the gestational period
2. Patients must be cranio-sacral therapy naive
2. Patients must be well integrated in the Swedish language
3. Patients should have well defined pregnancy-related pelvic girdle pain according to the European Guidelines of diagnosis and treatment of Pelvic Girdle Pain
4. They have to have experienced an evening pain (according to the patient-kept diary) of more than 40 mm (visual analogue scale [VAS]) during the baseline week to be eligible

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
120

Key exclusion criteria
1. Cranio-sacral therapy experience
2. Other pain conditions
3. Systemic disorders

Date of first enrolment
24/08/2009

Date of final enrolment
15/08/2010

Locations

Countries of recruitment
Sweden

Study participating centre
The Sahlgrenska Academy,
Göteborg
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Sponsor information

Organisation
The Health and Medical Care Committee of the Region of Västra Götaland (Sweden)

Sponsor details
Regionens Hus
Gothenburg
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S-405 44

Sponsor type
Government

Website
http://www.fou.nu/is/vgregion/ansokan/26671

ROR
https://ror.org/00a4x6777

Funder(s)

Funder type
Government

Funder Name
The Health and Medical Care Committee of the Region of Västra Götaland (Sweden) (ref: VGFOUREG-26671)

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?
Results article	results	01/07/2013		Yes	No