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

Submission date	Recruitment status	[_] Prospectively registered
22/05/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/06/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/10/2012	Pregnancy and Childbirth	

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-5463

Study information

Scientific Title

Study objectives
Pelvic girdle pain generally arises in relation to pregnancy, trauma or reactive arthritis. Pain is experienced between the posterior iliac crest and the gluteal fold, particularly in the vicinity of the sacroiliac joints. The pain may radiate in the posterior thigh and can occur in conjunction with or separately in the symphysis. The endurance capacity for standing, walking, and sitting is diminished. After pregnancy, problems are serious in about 7%, causing severe discomfort and reducing ability to work.

Null hypothesis: there is no difference in efficacy of acupuncture with penetrating needles or non-penetrating needles as an adjunct to standard treatment for the treatment of pelvic girdle pain in pregnant women.

Alternative hypothesis: there is a difference in efficacy of acupuncture with penetrating needles or non-penetrating needles as an adjunct to standard treatment for the treatment of pelvic girdle pain in pregnant women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ethics approval received from the Regional Ethics Committee in Gothenburg on the 20th February 2006 (ref: 059-06).

Study design
Single-blind, randomised controlled interventional 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
Well-defined 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 standardized 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 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 as well as acupuncture. 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 12 acupuncture treatments with penetrating needles for eight weeks
Group 2 will get 12 acupuncture treatments with non-penetrating needles for eight weeks

Local acupuncture points will be selected individually after diagnostic palpation to identify sensitive spots. A total of 10 segmental points and 7 extra-segmental points will be used. The penetrating needles (Hegu: Hegu AB, Landsbro, Sweden) or the non-penetrating needles (Asiamed GmbH & Co., Konrad Streitberger is the developer) are made of stainless steel (Ø0.30). The penetrating needle is inserted intramuscularly to a depth of 15-70 mm to evoke needle sensation, described as tension, numbness and often a radiating sensation from the point of insertion, reflecting activation of muscle-nerve afferents. The Streitberger needle pricks the skin but it does not penetrate the skin. Both needles are left in situ for 30 minutes and manually stimulated every ten minutes. Treatment is given twice a week over four weeks and once a week over four weeks. Foetal heart rate, maternal heart rate and blood pressure are monitored before and after all acupuncture treatments.

Intervention Type
Other

Phase
Not Specified

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])
2. Health functioning (EuroQoL questionnaire)
3. Recovery from symptoms as assessed by an independent examiner
4. 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%

Overall study start date
01/06/2006

Completion date
15/05/2007

Eligibility

Key inclusion criteria
1. Healthy women who have completed between 12 - 29 weeks of the gestational period
2. Patients must be well integrated in the Swedish language with singleton fetuses
3. Patients should have well defined pregnancy-related pelvic girdle pain
4. Patients must be acupuncture naive
5. They have to have experienced an evening pain (according to the patient-kept diary) of more than 50 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. Acupuncture experience
2. Other pain conditions
3. Systemic disorders
4. Contraindications to treatment

Date of first enrolment
01/06/2006

Date of final enrolment
15/05/2007

Locations

Countries of recruitment
Sweden

Study participating centre
The Sahlgrenska Academy,
Göteborg

Sweden
405 30

Sponsor information

Organisation
University of Gothenburg (Sweden)

Sponsor details
KK East Hospital
Göteborg
Sweden
416 85

Sponsor type
University/education

Website
http://www.fou.nu/is/vgregion/ansokan/5463

ROR
https://ror.org/01tm6cn81

Funder(s)

Funder type
Government

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

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	01/12/2008		Yes	No