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Group care exercise class vs individual physiotherapy care for the treatment of pelvic and back pain in pregnancy

Submission date
19/01/2009

Recruitment status
No longer recruiting

Registration date
24/03/2009

Overall study status
Completed

Last Edited
24/03/2009

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
N/A

Study information

Scientific Title
Randomised controlled trial for the treatment of pelvic girdle pain in pregnancy

Acronym
GRIP trial (GRoup therapy verses Individual therapy for Pelvic girdle pain in pregnancy)

Study objectives
We aim to conduct a prospective open label randomised controlled trial to test the hypothesis that following initial assessment by a physiotherapist, group care exercise class is as effective in reducing pain as individual physiotherapy care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cork University Teaching Hospitals Clinical Research Ethics Committee, approved on 16/01/2009

Study design
Open-label randomised controlled single-centre 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 in pregnancy

Interventions
Following initial assessment participants will be randomly allocated to one of two treatment groups (randomisation ratio 1:1). Patients will be asked to keep a pain score diary where they

will record their pain score using a visual analogue scoring system. Patients will be asked to record a score every morning and every evening during the treatment course. The first treatment in both treatment arms will be one week following initial assessment.

Individual care group: Three sessions/week, approximately 45 minutes/session
Group care group: Weekly group exercise classes for 4 weeks (1h/class), focusing on core stability and strengthening exercises.

In both treatment groups pain scores will be followed up for 1 week post last treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
A reduction in the current intensity of PGP related to motion on a 100-point visual analogue scale (VAS) in the morning and in the evening recorded in the patient's diaries (0 represented no pain and 100 represented worst conceivable pain).

Secondary outcome measures
1. Admission to hospital with PGP during the course of the current pregnancy
2. Frequency of sick leave from work due to PGP from initial diagnosis until delivery
3. Representation at the physiotherapy department during the trial period (From initial assessment and diagnosis until the last treatment session)
4. Representation at the physiotherapy department after the trial period (From last treatment session until delivery)
5. Number of patients requiring the combination of crutches and Tubigrip® (elasticated tubular support bandage) during the antenatal period
6. Number of patients induced or delivered earlier than their estimated date of delivery due to severe PGP
7. Patient satisfaction measured via the Client Satisfaction Questionnaire (CSQ-18B) following the third treatment
8. Patient specific functional scale (PSFS). This will be measured at initial assessment and following the third treatment. The PSFS will measure patient's ability to perform 3 out of the 4 following tasks. Each of the 3 tasks chosen by the patient is measured out of 10 and then an average score is taken. A drop of 2 in one of the tasks will be considered as indicating an improvement. A drop of 3 in the overall average of the 3 tasks will also be considered as indicating an improvement.
The 3 tasks will be chosen from:
a. Turning over in bed
b. Climbing stairs
c. Sitting more than 10 minutes
d. Standing more than 10 minutes

9. Active straight leg raise. This will be measured at initial assessment and following the third treatment. While lying supine with a wedge placed under the women's right side, the patient will be asked to alternatively raise her legs. The patient will be asked to give a score out of 5 for the difficulty level. Scores are indicated as follows
5 = Unable to perform

4 = Very Hard
3 = Moderately Hard
2 = Somewhat Hard
1 = Minimal Difficulty
0 = No Difficulty

The total score will be marked out of 10 (5 for each leg). A drop in the score of 3 will be considered as indicating an improvement.

10. Gestational age at delivery
11. Birthweight at delivery
12. Mode of delivery: Either normal vaginal delivery, instrumental delivery or caesarean section

Overall study start date
01/04/2009

Completion date
31/03/2010

Eligibility

Key inclusion criteria
Pregnant women (primigravida and multigravida; no age limits) from 20-35 weeks of gestation attending Cork University Maternity Hospital (CUMH) low risk antenatal clinics who are referred to the physiotherapy department by their health care provider or following self referral with back pain or pelvic pain will be assessed for inclusion in the trial. Women referred to the physiotherapy department with symptoms of pelvic girdle pain (PGP) will be assessed on presentation by a one of six departmental physiotherapists specializing in women's health.

To make the diagnosis of PGP the following tests will be performed as per the European Guidelines on the diagnosis and treatment of Pelvic Girdle Pain and a pain history taken as detailed.

Sacroiliac joint assessment:
1. Posterior pelvic pain provocation test (P4)
2. Gaenslen's test
3. Compression of anterior superior iliac spines (ASIS)
4. Distraction Sacro-Iliac Joint (SIJ) pain provocation test
5. Assessment of Sulci depth in lumbar spine in neutral and extension

Functional pelvic test:
6. Active straight leg raise test (ASLR)

Pain history (according to the criteria of Ostgaard):
7. It is recommended that a pain history be taken with specific attention paid to pain patterns and irritability of PGP
8. There must be no nerve root syndrome
9. The severity of pain must be related to motion

The diagnosis of PGP will be made if the patient has two or more of criteria 1-4 (Laslett's criteria) in combination with a negative McKenzie and negative neurological examination. Criteria 5-9 will

be performed and assessed to try and improve diagnostic sensitivity and specificity as well as help exclude other pathologies that may cause pelvic and back pain.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
226

Key exclusion criteria
1. Women with other pain conditions, history of orthopaedic disease or surgery in the spine or pelvic girdle systemic disorders or if attending the high risk antenatal clinic in CUMH
2. Women who volunteered a history of sexual abuse at any point of the study
3. Women who do not speak English fluently
4. Women with non viable pregnancies
5. Women who have already received treatment for PGP outside of this trial
6. Pregnant women who present who will not be booking at CUMH for their pregnancy or are not resident in the South West of Ireland
7. Women with a history of severe PGP in previous pregnancies. Severe PGP will be defined as occurring less than 20 weeks gestation in a previous pregnancy or requiring crutches in a previous pregnancy or women with a history of PGP in two or more previous pregnancies.

Date of first enrolment
01/04/2009

Date of final enrolment
31/03/2010

Locations

Countries of recruitment
Ireland

Study participating centre
Anu Research Centre
Cork
Ireland
-

Sponsor information

Organisation
Cork University Maternity Hospital (Ireland)

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Sponsor type
Hospital/treatment centre

Website
http://www.ucc.ie/en/obsgyn

ROR
https://ror.org/04q107642

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Cork University Maternity Hospital (Ireland)

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