

Auricular acupuncture for treatment of low back pain and posterior pelvic pain in pregnancy

Submission date 02/02/2014	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 20/03/2014	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 19/06/2015	Condition category Pregnancy and Childbirth	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

About 45% of all pregnant women suffer lower back pain and/or pelvic girdle pain (LBPGP). This study seeks to evaluate the effect of auricular acupuncture (ear acupuncture) on the LBPGP suffered by pregnant women compared with placebo (dummy) auricular acupuncture and with standard obstetric care in the field of primary health care.

Who can participate?

Pregnant women (24 -36 weeks' gestation), aged at least 17 years, referred by the family doctors at about 20 primary care centres participating in the study, and forming part of the Andalusian Public Health System, in the provinces of Seville, Málaga and Cádiz, diagnosed with pregnancy-related LBPGP and who have not previously received auricular acupuncture.

What does the study involve?

Participants will be randomly allocated to one of four study groups:

1. Auricular acupuncture plus standard obstetric care group (VAAc)
2. Non-specific auricular acupuncture plus standard obstetric care group (NSAAc)
3. Non-specific placebo auricular acupuncture plus standard obstetric care group (PAAc)
4. Standard obstetric care group (SOC).

The VAAc, NSAAc and PAAc groups will receive treatment once a week for two weeks at three auricular acupuncture points (the VAAc group will receive acupuncture at specific points for lower back pain, and the NSAAc and PAAc groups will receive acupuncture at points non-specific to lower back pain). The SOC group will receive only standard obstetric care during the same period.

What are the possible benefits and risks of participating?

The benefits of participating in the study and of receiving VAAc will be pain relief and improved functional capacity and quality of life. All participants will benefit from the standard obstetric treatment. No major side effects are expected.

Where is the study run from?

The study will be conducted in the field of primary health care at about 20 primary care centres forming part of the Andalusian Public Health System, in the provinces of Seville, Málaga and Cádiz (Spain).

When is the study starting and how long is it expected to run for?

Recruitment will take place from February 2014 to December 2015, and the study will last until December 2016.

Who is funding the study?

Spanish Ministry of Health and Consumer Affairs (Carlos III Health Institute) (Spain).

Who is the main contact?

Dr Jorge Vas

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

PI13/00010

Study information

Scientific Title

Auricular acupuncture for treatment of low back pain (LBP) and posterior pelvic pain in pregnancy in primary care: study protocol for a multicentre randomised placebo-controlled trial

Acronym

AuriculopunctureLBP_Pregnancy

Study objectives

Our clinical hypothesis is that acupuncture applied via pressure needles inserted in the auricle (VAAc), associated with the usual obstetric care, can reduce the pain experienced by pregnant women with pain in the lower back and/or the posterior pelvic girdle (LBPGP), to a greater extent than is achieved by standard obstetric care alone in the field of primary health care. Additionally, the application of this technique improves patients' functional status and health-related quality of life, and moderates the consumption of drugs used in conventional therapy, thus reducing the associated iatrogenic effects without provoking significant iatrogenesis in itself. Secondly, VAAc associated with normal obstetric care has specific effects, achieving a greater reduction in the LBPGP suffered by pregnant women than that achieved with the application of pressure needles at nonspecific pressure points or with placebo needles at nonspecific points.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local Clinical Trials Committee (Comité Local de Ensayos Clínicos) Southern Area Health Management Sevilla (Area Gestión Sanitaria Sur de Sevilla), 20/04/2013

Primary study design

Interventional

Study design

Prospective multicentre randomised placebo-controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Lower back pain and/or pain in the posterior pelvic girdle

Interventions

A 4-hour workshop will be organised for all the midwives participating in the study, to demonstrate the implementation of the technique, the obstetric care to be provided and the study records to be kept.

Patients will be randomised to one of four groups:

1. Standard obstetric care (SOC)

The usual obstetric care for the treatment of lower back pain and posterior pelvic pain in pregnancy will include an explanation of their causes and of recommended self-care procedures, both to prevent pain and to reduce its intensity, together with training in specific stretching exercises for the back and the hamstrings. In addition, the women will be recommended to use paracetamol and/or visit their family doctor if the pain intensity becomes severe.

2. Verum auricular acupuncture (VAAc)

Auricular pressure needles 1.5 mm long and 0.20 mm in diameter (Pyonex Seirin, Shizuoka, Japan) will be applied to two standardised points (Shenmen and Kidney), and at a reflex point in the region of the auricle that classically represents the lumbar or sacral regions, and which will be detected by means of a probe calibrated at 250 grams of pressure.

3. Nonspecific auricular acupuncture (NSAAc)

The items used in the nonspecific auricular acupuncture group will be the same as in the VAAC group, but they will be applied at auricular points that are nonspecific for lower back pain or posterior pelvic pain, and which instead correspond to reflex points corresponding to anatomic locations in the ankle, wrist and shoulder.

4. Nonspecific placebo auricular acupuncture (PAAc)

The items used will be identical to those used in the VAAC group, but without the needle, and will be placed at the same nonspecific points as for the NSAAc group.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Reduction in pain intensity, according to the visual analogue scale (painVAS), at 2 weeks after the start of treatment.

Key secondary outcome(s)

1. Functional status with respect to LBPGP (according to the Roland-Morris lumbar disability questionnaire)
2. Health-related quality of life (SF12) at 2 weeks after the start of treatment
3. Reduction in pain intensity, according to the visual analogue scale (painVAS), at 12 and 48 weeks postpartum

Completion date

31/12/2016

Eligibility

Key inclusion criteria

1. Pregnant women (24 -36 weeks' gestation)
2. Aged at least 17 years
3. Diagnosed with pregnancy-related lower back pain and/or pain in the posterior pelvic girdle (LBPGP)
4. Who have not previously received acupuncture

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Pregnant women who began to suffer LBPGP before their pregnancy
2. Pregnant women with signs suggesting LBPGP secondary to inflammatory, infectious, traumatic, neoplastic or degenerative processes
3. Pregnant women receiving anticoagulation therapy or presenting dermatitis of the auricle

Date of first enrolment

01/02/2014

Date of final enrolment

31/12/2015

Locations**Countries of recruitment**

Spain

Study participating centre**Pain Treatment Unit**

Dos Hermanas

Spain

41701

Sponsor information**Organisation**

Spanish Ministry of Health and Consumer Affairs (Carlos III Health Institute) (Spain)

ROR

<https://ror.org/00y6q9n79>

Funder(s)**Funder type**

Government

Funder Name

Spanish Ministry of Health and Consumer Affairs (Carlos III Health Institute) (Spain)

Results and Publications

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?
Protocol article	protocol	16/07/2014		Yes	No