ISRCTN10634508 https://doi.org/10.1186/ISRCTN10634508

Correcting non cephalic presentation with moxibustion: Study protocol for a multi-centre randomised controlled trial in general practice

Submission date
02/04/2008

Recruitment status
No longer recruiting

Registration date
30/04/2008

Overall study status
Completed

Last Edited
14/08/2013

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
0053/2007

Study information

Scientific Title

Study objectives
A sensorial stimulation with moxibustion in the outer corner of the little toenail (BL67) produce a greater proportion of version in non-cephalic presentations than the usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Trials Ethics Committee of the Andalusian Regional Government. Date of approval: 26/02 /2008 (ref: acta 02/08)

Study design
Multi-centre randomised controlled trial with three parallel arms.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Non cephalic presentation of fetus

Interventions
All the study subjects will be given various postural recommendations.

The participants will be randomly allocated to the following three arms:

Arm A: True moxibustion (TM): The first intervention will be made at the Healthcare Clinic. This session (overseen by the responsible midwife) will serve as a training session for the friend or relative who is to apply the remaining sessions at home. The mother should lie down, face up, wearing comfortable clothing and with no pressure at the waist from buttons, belt, etc. and with her legs slightly bent at the knee. Heat will be applied for 20 minutes, by means of a moxa cone (a herbal preparation with Artemisia vulgaris) at point BL67 (Zhiyin), close to the outer angle of the little toenail. The heat will be applied from a distance of 1.5-3 cm, to ensure that the subject

notices a feeling of warmth in the zone, but without any pain or burning. The application site (right or left foot) will be alternated every 2 minutes, or more often if any untoward sensation of heat is felt. True moxibustion will be carried out once a day for two weeks, or until cephalic version occurs.

Arm B: False/sham moxibustion (SM): This procedure will be identical to that applied to the TM group except that the point stimulated will be a non-active one according to the principles of Traditional Chinese Medicine, point SP1 (Yinbai), close to the inner angle of the big toenail. False moxibustion will be carried out once a day for two weeks, or until cephalic version occurs.

Arm C: Control group, under observation (CG): The subjects in this group will receive the standard treatment, in accordance with the Andalusian Healthcare System Treatment Guide.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Moxibustion

Primary outcome measure
Rate of cephalic presentation at term.

Secondary outcome measures
1. Rate of cephalic presentation at week 38 of gestation (CP38), determined by echography
2. Number of days of treatment received until version occurs
3. Rate of caesarean sections
4. Security variables:
4.1. Increased rates of foetal cardiac rhythm change, followed-up until birth
4.2. Risk of premature birth
4.3. Changes in Apgar scores at 1 minute and at 5 minutes 1. Rate of cephalic presentation at week 38 of gestation (CP38), determined by echography
2. Number of days of treatment received until version occurs
3. Rate of caesarean sections
4. Security variables:
4.1. Increased rates of foetal cardiac rhythm change
4.2. Risk of premature birth
4.3. Changes in Apgar scores at 1 minute and at 5 minutes

Overall study start date
01/04/2008

Completion date
01/12/2010

Eligibility

Key inclusion criteria

1. Pregnant women
2. Aged at least 18 years
3. Foetus is in a non cephalic position (diagnosed by physical examination and by echography)
4. Gestational age of 33-35 weeks (estimated by echography)
5. Normal foetal biometry
6. Those who have signed their informed consent
7. Have not previously received moxibustion treatment to correct the position of their unborn baby

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
492

Key exclusion criteria
1. Twin pregnancy
2. Pelvic defect
3. Previous uterine surgery
4. Foetal malformation or chromosome disorder
5. Uterine malformation
6. Risk of premature birth (preterm uterine contractions and/or initial dilation or shortening of the cervix with a Bishop's score of 4)
7. Uterine fibromas >4 cm
8. Treatment with tocolytic drugs
9. Heart or kidney disease affecting the mother
10. Other pregnancy-related complications
11. Inability to complete the questionnaire or respond to the assessor's questions

Date of first enrolment
01/04/2008

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
Spain

Study participating centre
Centro de Salud
Dos Hermanas
Spain
41700

Sponsor information

Organisation
Andalusian Regional Ministry of Health (Spain)

Sponsor details
Avda de la Innovación s/n
Edif. Arena 1
Sevilla
Spain
41020

Sponsor type
Government

ROR
https://ror.org/03q4c3e69

Funder(s)

Funder type
Government

Funder Name
Andalusian Regional Ministry of Health (Project No. 0053/2007)

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	01/03/2013		Yes	No