

Alternative Labour Pain Strategies Study

Submission date 11/05/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 21/09/2005	Overall study status Completed	☐ Protocol
Last Edited 25/11/2010	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☒ 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

Protocol serial number

Project Reference Number 04/Q1606/70

Study information

Scientific Title

Acronym

ALPS

Study objectives

Does regular use of an established massage, breathing and visualization programme, from 36 weeks until birth, reduce maternal pain perception and pharmacological analgesia in labour, compared to the effects of standard antenatal preparation and placebo?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised placebo controlled parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Labour Pain Management

Interventions

Intervention: Massage group

The model is practised as follows: women attend a class at 35-37 weeks gestation with their chosen birth companion where the programme is introduced by the midwife/therapist. The importance of breathing awareness is emphasised and massage techniques are taught, synchronising them with breathing and visualisation. They are asked to practise this programme, with the help of a video, for at least 3 evenings a week, for about 30-45 minutes, until 39 weeks and then a combination of techniques every evening, until hospital admission for labour /induction. During labour in hospital, the intervention is supported by a self-selected group of midwives, who have successfully completed an accredited massage course and attended one information session on the needs and expectations of women in the placebo arm of the trial.

Placebo: Breathing/Visualisation

It is possible that the addition of an extra antenatal class specifically devoted to coping with pain in labour will improve outcomes for women in the Massage group regardless of the use of massage. Therefore, this "placebo" group will be included as a second comparison to test whether additional social support in the massage group accounts for any observed difference. Couples receive an additional antenatal class devoted to coping with labour, which offers breathing techniques and visualisation, without the use of massage. They are asked to practise this programme, for at least 3 evenings a week, for about 30-45 minutes, until 39 weeks and then a combination of techniques every evening until hospital admission for labour/induction. During labour in hospital, the intervention is supported by a self-selected group of midwives, who have successfully completed an accredited massage course and attended one information session on the needs and expectations of women in the placebo arm of the trial.

Control: Usual care

The women and companions in this group will be asked to attend the usual antenatal preparation classes that are currently available at the trial site. At present there are 4 two-hour classes.

Blinding to such visibly different options will not be possible. However, information offered to women will focus on the use of complementary strategies for coping with pain, rather than focusing only on the use of massage and will not emphasise, or imply superiority of, one form of care over another. Instead current lack of knowledge about what helps women to cope with labour will be emphasised. The use of a Placebo group guards against the potentially confounding factor of additional information, social support and other non-pharmacological strategies for pain management.

A self-selected group of trained midwives will care for women in all three arms of the trial. This has been done to ensure that:

1. All participants are cared for by professionals who have achieved the same level of knowledge and competence
2. Midwives are adequately trained to undertake the intervention in a safe and effective manner, as and when necessary during labour
3. Midwives are adequately informed to support couples in the placebo group

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The primary outcome measure will be self-reported labour pain. The visual analogue scale (VAS), a simple, widely used measure validated for use to assess overall labour pain, within 48 hours of birth will be given to all participating women to complete before transfer from labour care. The scale will be given to women during the second hour following birth when hormonal interactions that begin immediately following birth initiate maternal-infant contact and pain from perineal trauma is usually absent. This is ethically and physiologically preferable to use during labour, or to use of the more complex and time-consuming Magill Pain Questionnaire, that is also validated for such research.

Key secondary outcome(s)

Other methods of pain relief, obstetric interventions, birth outcomes, cord blood levels of stress hormones and women's satisfaction and sense of control.

Completion date

30/11/2005

Eligibility**Key inclusion criteria**

Eligible women will include all pregnant women booked for care in the study period except for listed exclusions.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Multiple pregnancy
2. Planned caesarean section
3. Medical problems that would preclude the use of massage techniques
4. Women who have previously used the massage programme
5. Women who have a strong preference for a particular form of pain relief
6. Women who do not speak fluent English
7. Women not intending to have a birth companion

Date of first enrolment

01/12/2004

Date of final enrolment

30/11/2005

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Horton Maternity Hospital

Oxford

United Kingdom

OX16 9AL

Sponsor information**Organisation**

Oxford Radcliffe Hospitals NHS Trust (UK)

ROR

<https://ror.org/03h2bh287>

Funder(s)

Funder type

Research council

Funder Name

Oxfordshire Health Services Research Committee (UK) (Application for Research Grant Reference - CM001)

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?
Results article	results	01/11/2008		Yes	No