ISRCTN16877725 https://doi.org/10.1186/ISRCTN16877725

Effect of first trimester crown rump length measurement on rates of induction of labour for postdates.

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/12/2008	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
SPGS 757

Study information

Scientific Title

Study objectives
The project is an RCT of the effect of first trimester ultrasound on rates of induction of labour for postdates. Currently it is widespread practice in most obstetric units in the United Kingdom to induce labour 14 days after the estimated date of delivery (EDD). While this has been shown to have a beneficial effect on perinatal outcome, it may cause consumer dissatisfaction as it is perceived to be a painful intervention in an otherwise normal pregnancy. Measurement of the biparietal diameter at 20 weeks gestation has been shown to improve the accuracy of gestational age assessment, and this should lead to a reduction in rates of induction of labour for postdates. Gestational age assessment using CRL in the 1st trimester is more accurate than the biparietal diameter and may further reduce the numbers requiring induction for postdates. There is an increasing shift to perform prenatal diagnosis in the first trimester. Those providing antenatal care may have to choose the best time at which a routine scan in pregnancy can be offered. If a first trimester ultrasound scan is shown to improve the customisation and therefore the appropriateness of obstetric care this would provide further evidence to justify its introduction as well as its use in screening for Down's syndrome, either with nuchal fold or as an adjunct to serum screening.
The objective is to determine whether an ultrasound scan in the first trimester of pregnancy will lead to more accurate assessment of gestational age and consequently lead to a reduction in the number of pregnancies induced at term and fourteen days. If this is the case then there will be cost savings for the NHS, as well as the reduction in unnecessary and potentially painful interventions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Pregnancy and childbirth: Childbirth

Interventions
The control group will continue with routine antenatal care with ultrasound performed for the usual indications.
The intervention group will have an ultrasound scan between 8 and 12 weeks gestation to measure the crown-rump length (CRL) and if there is a discrepancy of greater than 5 days between the estimated date of delivery (EDD) calculated form the last menstrual period and that by CRL the EDD will be revised to that derived by scan. The EDD will be entered in the patient's obstetric notes and all subsequent management decisions will be based on this assessment of gestational age.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Rates of induction of labour for postdates

Secondary outcome measures
1. The characteristics of labour with respect to the length of labour, the mode of delivery, the immediate perinatal outcome, analgesic requirements for labour and the overall client satisfaction with labour
2. Rates of gestation dependent events in pregnancy - false positive and negative outcomes from maternal serum screening
3. The management of early pregnancy complications

Overall study start date
01/02/1999

Completion date
30/09/2002

Eligibility

Key inclusion criteria
Women in the first trimester of pregnancy who do not require a first trimester ultrasound for any other clinical indication.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Added December 2008: 800 intended

Key exclusion criteria
Women will be excluded if there is a clinical indication for a first trimester ultrasound scan or if they refuse consent. Examples of the former would be if there was vaginal bleeding, uncertainty about viability of the pregnancy or the possibility of an ectopic pregnancy.

Date of first enrolment
01/02/1999

Date of final enrolment
30/09/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nuffield Department of Obstetrics and Gynaecology
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
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Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive South East (UK)

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 of uncompleted trial	01/02/2006		Yes	No